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FINAL STATEMENT OF REASONS

CALIFORNIA CODE OF REGULATIONS

TITLE 8: Division 1, Chapter 4, Subchapter 7, Group 16, Article 107,
Section 5155 of the General Industry Safety Orders

Airborne Contaminants

MODIFICATIONS AND RESPONSES TO COMMENTS RESULTING FROM THE 45-DAY PUBLIC COMMENT PERIOD

There are no modifications to the information contained in the Initial Statement of Reasons except for the following non-substantive modifications that are the result of public comments and/or Board staff evaluation. This action is a result of a withdrawal of proposed amendments to a chemical with reversion back to the existing regulatory requirement as explained below.

Ozone

In a letter dated March 24, 2009, Ken Nishiyama Atha, federal OSHA Regional Administrator (Region IX), indicated that the proposed amendments to the PEL for ozone taken in their entirety, including a footnote allowing for exclusion of ambient levels of ozone in the newly proposed Ceiling limit, would not be as effective as the federal standard in protecting employees in the workplace from the health hazards of ozone. Discussions with federal OSHA staff indicated their belief that simply restoring the existing 8-hour TWA of 0.1 ppm to the proposal, equivalent to the OSHA PEL, to be in effect, alongside the proposed Ceiling limit with the proposed footnote allowing exclusion of ambient ozone concentrations from compliance determinations, would not be at least as effective as the OSHA PEL of the 8-hour TWA limit by itself.

In light of this determination by federal OSHA, the Occupational Safety and Health Standards Board (Board) is withdrawing the amendments proposed to the PEL for ozone and the corresponding proposed revision of Section 5155(p) for further evaluation and may reconsider the proposal at a future date if the concerns of federal OSHA with it being at least as effective as the federal standard can be addressed.

SUMMARY OF AND RESPONSES TO ORAL AND WRITTEN COMMENTS

I. Written and Oral Comments Related to "All" Substances in the Rulemaking Proposal

Ken Nishiyama Atha, Regional Administrator-Region IX, Occupational Safety and Health Administration, by letter dated March 24, 2009.

Comment: Mr. Atha advised that with respect to the substances in this rulemaking other than "ozone", the proposed PEL values were at least as effective as the federal OSHA counterparts. Regarding Mr. Atha's comment on ozone, refer to page 1 of this document under the heading "Ozone".

Response: The Board has modified the proposal, as stated on page 1 of this document, regarding ozone. The Board thanks Mr. Atha for his participation in this rulemaking process.

Robert Dowell, Plasma Technology, Inc. (PTI), by letter dated March 6, 2009

Comment: Given the time that has elapsed since the discussions of the Division of Occupational Safety and Health (Division's) Airborne Contaminants Advisory Committee (Committee) on the current proposal, and the availability of a superior, defensible evaluation process; workers, business and the public would be better served by reviewing the chemicals under consideration using the current PEL process. PIT urgently requests that the Standards Board defer adoption of the PELs for nickel and for other compounds and instead use the current PEL process because it will result in scientific, well-documented recommendations.

Response: While the advisory committee process which considered the substances for which new or revised PELs are being proposed may not be exactly the same as the current process, there was substantial and sufficient scientific rigor associated with the process of that former advisory committee to warrant consideration of PELs based on its recommendations. The Board also notes that at its meeting on May 18, 2005, the Division took comments from a number of interested parties on issues of both the committee's health-based recommendations, as well as questions of their cost and feasibility, and that, as detailed in the Initial Statement of Reasons (ISOR), those comments, as well as, in some cases, additional information provided by the commenters after that meeting, were factored into proposed modifications of several of the Committee's recommendations for PELs in this proposal. The Board believes that deferring their consideration while they are reviewed again in the Division's current PEL process is not warranted.

Bill Kelly, Unifrax Corporation, at the March 19, 2009 public hearing

Comment: Bill Kelly, RCFC, said that his organization endorses the current Health Expert Advisory Committee (HEAC) and PEL development process. He said the prior advisory committee did not take feasibility into account in its recommendation of a PEL of 0.1 f/cc for refractory ceramic fiber.

Response: See the response to Robert Dowell's written comment, above.

Barbara Kanegsberg, BFK Solutions, by letter dated March 9, 2009 and at the March 19, 2009 public hearing

Comment: Barbara Kanegsberg verbally summarized her written comment that the HEAC meetings currently underway to develop health-based PEL recommendations operate under a more formalized process than the Committee did for the current proposal. Barbara Kanegsberg said in her letter that the process which led to the current proposal did not follow the rigorous, standardized approach of the current HEAC process which has been in place for almost two years, and the recommendations were not promptly passed on to the Standards Board. Board action on the proposed worker exposure limits should be postponed until the proposal has been re-evaluated by the current Cal/OSHA PEL process, including evaluations by the HEAC and the FAC (Feasibility Advisory Committee).

Response: See the response to Robert Dowell's written comment, above.

Michael Smith, WorkSafe, at the March 19, 2009 public hearing

Comment: Michael Smith summarized his written comments.

Response: See the responses to Michael Smith's written comments under the individual substances commenters' address.

II. Written and Oral Comments Related to "Individual" Substances in the Rulemaking Proposal

Allyl glycidyl ether

Julia Quint, by letter dated March 18, 2009

Comment: Julia Quint supports the proposed PEL of 0.2 ppm 8-hour time-weighted average (TWA). She said the proposed PEL will help to prevent a material impairment of health of a potentially large number of workers who use epoxy resins that contain allyl glycidyl ether as a diluent. She said that the proposed PEL based on sensory irritation is appropriate since there are no relevant chronic toxicity data on this chemical.

Response: The Board thanks Julia Quint for her participation in this rulemaking process.

Michael Smith, WorkSafe, and 12 Co-Signers, by letter dated March 19, 2009

Comment: The commenters support the proposed PEL, especially in light of the chemical being a High Production Volume Chemical. However, they question the rounding of the calculated recommendation of 0.17 ppm to 0.2 ppm by the Committee.

Response: The Board thanks the commenters for their statement of support for the proposal. The Board recognizes the commenters' concern with the Committee's rounding up of the calculation of the PEL value to prevent respiratory irritation based upon the formula of multiplying the RD_{50} times 0.03 as detailed in the minutes of the Committee's discussion and in the Initial Statement of Reasons. The Board views the

rounding of the calculation result in this case by the Committee as recognition that it is not a fine line between an exposure level that is completely safe, and one that may pose a health risk.

1-bromopropane, n-propyl bromide

Katy Wolf, Director, Institute for Research and Technical Assistance, at the March 19, 2009 public hearing

Comment: Katy Wolf spoke in support of the proposed PEL for 1-bromopropane and summarized her written comments submitted February 25, 2009. She suggested that instead of the proposed value of 5 ppm, the PEL should be set at 3 ppm, or lower. She also requested that the Board consider establishing a ceiling limit of 10 or 15 ppm. Board Member Frisch asked Katy Wolf if there is a basis for her recommendation of a ceiling limit of 10 or 15 ppm for 1-bromopropane. Katy Wolf responded that she was not aware of a quantitative basis for her suggestion of a ceiling limit of 10 or 15 ppm for 1-bromopropane.

Response: As detailed in the response to the comments of Richard Morford and Nancy O'Malley regarding this substance, air sampling data is available indicating that 5 ppm is an appropriate level for a PEL based on feasibility of achievement with solvent cleaning equipment. The Board appreciates the concern of the commenter in suggesting a short term exposure limit or ceiling limit to better control exposures from intermittent operations as suggested in her letter summarized below. However, such a limit was not discussed by the Committee, and the Board does not have specific information to support proposal of a short term limit or ceiling limit for 1-bromopropane at this time.

Richard Morford, EnviroTech International, at the March 19, 2009 public hearing

Comment: Richard Morford summarized his written comments responded to below. He said that EnviroTech had worked with the U.S. Environmental Protection Agency and OSHA regarding safe workplace exposure levels for 1-bromopropane. He said that EnviroTech's corporate policy is that exposure to any chemical should be kept as low as possible. He said that based on feasibility and the need of employers for a margin of assurance or "headroom" between likely exposure levels and the PEL in order to be confident of compliance, that the PEL for 1-bromopropane should be 10 ppm, or possibly 15 ppm. He said there was no clear rationale for the 10 ppm Threshold Limit Value of the American Conference of Governmental Industrial Hygienists, and the Initial Statement of Reasons for the rulemaking did not make reference to the 18 to 25 ppm limit recommended by the EPA in its Federal Register Notices for 1-bromopropane with regard to the Significant New Alternatives Program (SNAP). He said that since the Committee developed its PEL recommendation for 1-bromopropane there have been approximately 70 articles published that support a higher PEL.

Response: See the responses below to Richard Morford's written comments.

Board Member Jonathan Frisch, at the March 19, 2009 public hearing

Comment: Board Member Frisch asked that the Division include more recent scientific studies in the Final Statement of Reasons discussion for 1-bromopropane. He also requested a more complete explanation of why the PEL proposed was rounded up to 5 ppm rather than being rounded down to 3 ppm or up to 4 ppm.

Response: With regard to more recent scientific information on 1-bromopropane, Division staff, in the course of developing the proposed PEL, did survey the scientific literature for substantial new information that might have altered the deliberations and conclusions of the Committee which recommended a PEL of 1 ppm, but also discussed a PEL of 3.3 ppm using the approach noted by Julia Quint in her written comment on the proposal. As explained further in response to the third written comment of Richard Morford (RM3) below, the Division in that survey did not identify any scientific information developed or published since the meetings of the Committee that would have altered the outcome of its deliberations. With regard to the rounding of the PEL to 5 ppm from the 3.3 ppm level discussed by the Committee, the Division, in developing the Final Statement of Reasons, is confirming the proposal for a PEL of 5 ppm not based on rounding from 3.3, as originally proposed, but instead based on air sampling data contained in the Federal Register SNAP Notices for 1-bromopropane in 2003 and 2007 as discussed in detail in response to the written comments of Richard Morford (RM1 and RM2).

In addition, the Board adopts comments made by Julia Quint at the March 19, 2009 public hearing in response to Board Member Frisch's comment. Julia Quint said that in preparing her written comments on the proposal, she conducted literature searches on a number of the substances being considered for new or revised PELs, including 1-bromopropane. She said that she also reviewed the EPA Federal Register Final Rule Notice in May 2007 for SNAP on 1-bromopropane. She said that the recency of the 2007 EPA Notice made it a good basis for newer information, but that she was surprised to find that no newer studies had been cited by EPA than what the Committee had considered in developing its recommended PEL. Julia Quint also urged the Board to consider risk assessment procedures that are consistent with those used by other government agencies.

Richard Morford, EnviroTech International, at the March 19, 2009 public hearing

Comment: Richard Morford asked that the Board review the 2003 EPA SNAP Notice in the Federal Register in which the agency disagreed with and criticized the HESIS publication from 2003 on 1-bromopropane with regard to the process used to derive a recommended workplace exposure limit and its application of uncertainty factors. He said this reflects the problem of what research and criteria to use in establishing uncertainty factors and that it is a contentious issue among toxicologists.

Response: As indicated on page 33296 of the Federal Register of the June 3, 2003 EPA Notice for the Significant New Alternatives Program (SNAP), in 2001 EPA's Office of Atmospheric Programs solicited comments regarding ICF Consulting's analysis and derivation of a recommended Acceptable Exposure Limit from the State of California, Department of Health Services, Hazard Evaluation System & Information Service (HESIS) and several other expert sources. In her role then as Chief of HESIS, Julia Quint responded to this request. On page 33297 of the June 3, 2003 Federal Register, EPA responded to Julia Quint's comments with regard to uncertainty factors and other methodological approaches used by ICF in their risk assessment. While the Federal Register reflects EPA's questioning of Julia Quint's comments on the ICF risk assessment for an Acceptable Exposure Level (AEL) for 1-bromopropane for SNAP, in the 2003 Federal Register Notice it is not apparent that EPA disagreed with and criticized the HESIS risk assessment as the commenter suggests. As discussed in response to the written comment of Richard Morford on the health basis of the proposed PEL (Comment RM3), the purpose for which the Acceptable Exposure Limit was developed by ICF is not the same as the purpose of a PEL. Therefore, EPA's questioning of Julia Quint's comments on the ICF risk assessment conducted for development of the Acceptable Exposure Level for EPA are not directly relevant to the HESIS risk publication and its

recommended workplace exposure limit of 1 ppm for 1-bromopropane to which the commenter is apparently referring.

Katy Wolf, Institute for Research and Technical Assistance (IRTA), by letter dated February 25, 2009

Comment: IRTA supports the addition of a PEL for 1-bromopropane and urges the Board to reduce the PEL below the proposed 5 ppm to be more protective of workers and members of the communities surrounding facilities where it is used. IRTA would prefer a PEL of 1 ppm based on the recommendations of HESIS and OEHHA. IRTA also requests that a Short Term Exposure Limit (STEL) be adopted to protect workers who use the chemical intermittently over the course of the workday in aerosols, spray bottles and spray equipment.

Response: See the response above to the comments of Katy Wolf at the public hearing on March 19, 2009.

Rick Kreutzer, California Department of Public Health, by letter dated March 16, 2009

Comment: On July 17, 2007, HESIS recommended to the Division an 8-hour TWA PEL for 1-bromopropane of 3 ppm. This health based recommendation was based upon the finding of adverse effects on reproductive function in experimental animals, accounting for interspecies and intraspecies variability. In addition, recent case reports published by the U.S. Centers for Disease Control and Prevention (Morbidity and Mortality Weekly Report 57(48):1300-1302, December 5, 2008) provide evidence that 1-bromopropane can also produce severe neurological damage in exposed workers. Based on the known and suspected serious health effects of 1-bromopropane, and a structurally similar compound, dibromochloropropane, which was found to have caused sterility in workers, he recommends adoption of a PEL of 3 ppm for 1-bromopropane. Although this value differs only slightly from the proposed value of 5 ppm, it is derived directly from the toxicological data using conventional risk assessment methods and is, therefore, more defensible.

Response: The Board appreciates the long term contribution of the California Department of Public Health, primarily through HESIS, to the PEL development process, and specifically to the Committee's consideration of a PEL for 1-bromopropane. Essentially, the Board is proposing to adopt a PEL of 5 ppm, based upon the value recommended in the commenter's letter, adjusted to take into account air sampling data indicating that 5 ppm is an appropriate level for a PEL based on feasibility of achievement with solvent cleaning equipment as detailed in the responses to the written comments of Richard Morford and Nancy O'Malley.

Julia Quint, by letter dated March 18, 2009

Comment: Julia Quint opposes the proposed PEL of 5 ppm 8-hour TWA for 1-bromopropane and instead supports a PEL of 3 ppm based on quantitative risk analysis to protect against male and female reproductive damage and developmental damage. There is no scientific basis for rounding to the proposed PEL of 5 ppm, rather than down to a value of 3, from the value of 3.3 ppm discussed in the Initial Statement of Reasons. The quantitative risk assessment methods used to derive a PEL of 3 ppm (from the calculated value of 3.3 ppm) are consistent with those used by OSHA, EPA, and OEHHA and by the current Cal/OSHA HEAC. She notes that the ACGIH TLV of 10 ppm for 1-bromopropane does not have a clear scientific basis or rationale and was not derived using quantitative risk assessment methods consistent with those used by OSHA, EPA or OEHHA. The PEL of 156 ppm recommended in the study of Stelljes and

Wood is not adequately protective for reproductive effects. This is due, she says, in part, to the fact that the authors did not use uncertainty factors to reduce the benchmark dose level they determined to account for uncertainty in the data due to interspecies and intraspecies variability. Also, the Stelljes and Wood calculation of the benchmark dose (BMD) is not consistent with, and is less health conservative than, the policy of OEHHA (Office of Environmental Health Hazard Assessment in Cal/EPA).

With regard to an 18 ppm Acceptable Exposure Limit (AEL) identified by EPA as a starting point in their Significant New Alternatives Program (SNAP) assessment for substances with reduced ozone-depleting potential, it used the same non-conservative approach to calculating the BMD as Stelljes and Wood, and EPA did not adopt an AEL in the May 30, 2007 Federal Register notice on 1-bromopropane.

Julia Quint pointed out that to derive the AEL of 18 ppm, EPA applied an interspecies uncertainty factor of 3 instead of 10 to the BMD data based without explanation on a lower blood/air partition coefficient for 1-bromopropane in humans (7.1) compared to rats (11.7). But, in the absence of supporting human metabolic and kinetic data, she feels that the reduction of the interspecies uncertainty factor based on speculation that the delivered dose may be higher in rats than in humans is not warranted.

Julia Quint is concerned that 1-bromopropane is a structural analog of dibromochloropropane, ethylene dibromide, and 2-bromopropane, all three of which she says have caused reproductive damage in humans. She notes that based on their toxicity, DBCP and EDB, both pesticides, have been banned in California. She notes also that use of 1-bromopropane is growing in different industrial sectors and that it is being marketed for use in dry cleaning. Finally, she believes that safer alternatives, including water based cleaners, exist for most uses of 1-bromopropane.

Response: The Board believes a PEL of 5 ppm 8-hour TWA for 1-bromopropane is appropriate based on the risk assessment and health based recommendation of 3.3 ppm noted by Julia Quint and detailed in the Initial Statement of Reasons, and modified for cost and feasibility considerations based on air sampling data contained in the Federal Register SNAP Notices for 1-bromopropane in 2003 and 2007 as discussed in detail below in response to written Comments RM1 and RM2 of Richard Morford**.**

Michael Smith, WorkSafe, and 12 Co-Signers, by letter dated March 19, 2009

Comment: The commenters oppose the proposed PEL of 5 ppm and support the PEL of 1 ppm recommended by the Committee. The commenters believe there is no basis for rounding up to 5 ppm from the value of 3.3. ppm presented to the Committee by then HESIS Chief Julia Quint. He details the basis and the calculation used to arrive at the 3.3 ppm recommendation. He notes that the 3.3 ppm value does not in fact rely on the Ichihara study, so concerns with that study indicated in the ISOR to be one of the reasons for rounding to a value of 5 ppm are irrelevant. Expressing concern with the potential for extensively increased use and employee exposure to this substance in California, the commenters state support for the Committee's original recommendation of 1 ppm based on OEHHA interim Reference Exposure Level (REL) adapted for worker exposure.

Response: As detailed in the response to the written comments of Richard Morford and Nancy O'Malley, air sampling data is available indicating that 5 ppm is an appropriate level for a PEL based on feasibility of achievement with solvent cleaning equipment. The Board recognizes the concern of the commenters with the potential for increasing use of 1-bromopropane in California and is confident, consistent with its focus

on emerging chemical hazards, especially those with concern of reproductive effects, that HESIS will keep the Division apprised of new information on exposure and health risks with this substance as it develops.

Richard Morford, EnviroTech International, Inc., by letter dated March 19, 2009

Comment RM1: Normal open top vapor degreasing systems as well as laundry dry cleaning systems operate at workplace exposure levels averaging 4 to 6 ppm. Currently, degreasing is the main use of 1-bromopropane in California and it is being tested as a substitute for perchloroethylene in laundry dry cleaning which is in the process of being phased out. As shown on page 30151 in the May 30, 2007 Federal Register Notice on 1-bromopropane published by the U.S. Environmental Protection Agency (EPA), data shows that 88% of over 500 samples taken at vapor degreasing operations were below 25 ppm, with 81% below 18 ppm, and 70% below 10 ppm.

EnviroTech conducted studies at 25 vapor degreasing operations and found workplace exposure levels from 0.13 ppm in vacuum machines to about 22 ppm in older open top vapor degreasers which are no longer in use, with the average of all exposures being 6 ppm. This data agrees with the data reported by U.S. EPA, in that the majority of vapor degreasing operations operate with workplace exposure levels under 10 ppm.

Further, in a recent study at an aerospace manufacturer, 24/7 monitoring of degreasing operations in one of the largest degreasers in the country were consistently found to be 5 ppm. As the data shows, the average degreasing operation, no matter what the size of the degreaser, will operate at or above the proposed 5 ppm limit. For this reason, and since industrial hygienists routinely mark up the PEL by 50% in order to help ensure that a workplace is reliably in compliance, the 5 ppm limit will be a defacto ban on the use of 1-bromopropane based solvents in vapor degreasing.

1-bromopropane is being tested as a dry cleaning agent and an exposure study at a test location in California found a workplace exposure of 3 to 4 ppm for the worker loading and unloading clothes in the machine, but exposures might be higher when more than one machine is present in the workplace. Also, a study in a Pennsylvania dry cleaning plant showed a workplace exposure in the range of 3 to 6 ppm when recommended work practices were used and a workplace exposure of about 18 ppm when good work practices were not used.

Response: The EnviroTech air sampling results cited by Richard Morford appear to be highly consistent with those he cites in the 2007 EPA Federal Register Notice in showing that most operations using 1-bromopropane in California are close to, or are already meeting, the proposed PEL of 5 ppm. No compelling technical or cost barriers to widespread compliance with a 5 ppm PEL for 1-bromopropane were cited by Richard Morford (see Comment RM2, below, for additional discussion on this point). Similarly, data in the comment for air sampling of a dry cleaning operation using 1-bromopropane, supports feasibility of the proposed PEL of 5 ppm for the dry cleaning industry.

In addition, air sampling data presented in the EPA Federal Register Notice of May 30, 2007 on page 30152, apparently from the same data set as that cited by Richard Morford on page 30151 of the same document with regard to cleaning operations using 1-bromopropane, indicates that in the study with 500 air samples taken, 56% of the results were at or below 5 ppm:

> In solvent cleaning equipment, exposure data show that nPB (1-bromopropane) can meet an exposure level well below 25 ppm, even at levels of 5 ppm or less, the majority of the

> time (U.S. E.P.A. 2003, ICF, 2006a). Concentrations of nPB emitted from industrial solvent cleaning equipment were measure(d) to be below 25 ppm in roughly 88% of more than 500 samples, below 18 ppm in 81% of these samples, and at or below 5 ppm in 56% of these samples.

Comment RM2: In order to operate consistently under 5 ppm, the only option available to manufacturers using 1-bromopropane based solvents would be capital investment in airless degreasing technology. As a manufacturer of such units, the cost to replace the smallest open top degreaser with an airless system of similar capacity would be at least $100,000. Larger airless systems can cost between $500,000 and $800,000 while the more traditional open top degreasers can cost $100,000 to $350,000. Airless systems also can increase energy usage and cost by at least 30%. Maintenance costs for airless and aqueous systems can also be typically 15% higher. Airless and aqueous cleaning systems also require significantly more space than open top degreasers. Specification requirements can prevent aerospace companies from using water based cleaning.

Response: Extensive air sampling data cited in Richard Morford's letter and detailed in the response to the preceding Comment RM1, shows that most exposures in California to 1-bromopropane are already likely to be at, near, or well below a PEL of 5 ppm. Individual employers will need to assess the likely worst case exposure in their particular workplace to determine if they may need to take additional steps to reliably maintain exposures to 1-bromopropane below 5 ppm. In the extensive air sampling data found on page 30151 in the EPA May 30, 2007 Federal Register Notice cited in the comment letter (see Comment RM1), along with the results noted on page 30152 of the same Federal Register Notice and discussed in response to the comment above, exposures to 1-bromopropane were found to be below 10 ppm in roughly 70% of one set of samples (page 30151) and below 5 ppm in 56% of the other set (page 30152). Taken together, these results suggest that only an additional 15% of exposures may be greater than 5 ppm but less than 10 ppm and thus requiring some additional controls to comply with the proposed PEL of 5 ppm. The air sampling data in the 2007 Federal Register Notice suggests an additional 20% of exposures perhaps exceeding 10 ppm would require more extensive control measures. The Board believes this data supports industry feasibility of compliance with the proposed PEL of 5 ppm. While the commenter cites substantial potential costs associated with an apparently small number of employers coming into compliance with a PEL of 5 ppm, no suggestion as to how many California employers may face these types of cost is provided, while the sampling data referred to suggests it will be a relatively small number, if any at all, given the large proportion of operations the data cited suggests are already at, near, or below 5 ppm. Taking the information above as a whole, the Board concludes that the proposed PEL of 5 ppm is both technically and economically feasible for industries using 1-bromopropane in California.

Comment RM3: EnviroTech supports the recommendation of the U.S. EPA of 18 to 25 ppm as a workplace exposure limit for 1-bromopropane. The California proposal lacks stakeholder input, has not considered all the relevant and latest scientific information available, and is based on reports that are out of date. The California proposal includes many inaccuracies and is based on assumptions which have been shown to be wrong in the time period since their publication six years ago.

From 2003 through 2009, a wealth of scientific information concerning 1-bromopropane was easily available to the agency at no cost at the EPA docket for their assessment published in the Federal Register of May 30, 2007. This docket contains an up to date collection of published and private toxicity studies regarding 1-bromopropane, all of which are easily available to the public on-line at no cost.

Response: The Board has been aware of the discussion by U.S. EPA in its Federal Register Notices for 1-bromopropane of an Acceptable Exposure Limit (AEL) for 1-bromopropane of 18 to 25 ppm (8-hour TWA). However, it is important to note, as stated on page 30150 of the Federal Register of May 30, 2007, EPA that its derivation of an AEL with a lower limit of 18 ppm is valid "as a starting point" in the development of a recommended acceptable exposure limit. On page 30145 and elsewhere in the May 30, 2007 Federal Register Notice, EPA did not in fact formally recommend an AEL for 1-bromopropane. Most significantly, however, even if EPA had formally recommended an AEL for 1-bromopropane, it is important to recognize the different purpose the AEL is intended to serve, compared to a PEL. A PEL is set for the sole purpose of protecting worker health, subject to limitations of feasibility. In contrast, the purpose of the AEL, within the context of EPA's program to review and approve substitutes for ozone depleting substances, is to determine if a substitute would not present a substantially greater risk to public health and the environment than the substances it might replace, or than other available substitutes (May 30, 2007 Federal Register, pages 30142 and 30158). Thus, the AEL is not intended as a necessarily maximally protective workplace exposure limit for a substance, but rather is a tool EPA uses in determining if a substitute, in particular uses (such as 1-bromopropane), for ozone depleting substances does not present a substantially greater health risk than the substances which it is proposed to replace. This is a lower standard than for which PELs are promulgated. PELs are expected to be protective of worker health without regard to comparison to the risks posed by other substances, subject to limitations of industry feasibility. As EPA states on page 30158 of the 2007 Federal Register Notice in response to a comment that OSHA, and not EPA, has the jurisdiction to develop workplace chemical exposure standards:

> As an initial matter EPA notes that it has not established an AEL applicable to the workplace in this rule. Rather, EPA reviewed the available information to determine what a safe workplace exposure might be in order to determine whether use of nPB (1-bromopropane) in the solvent cleaning sector poses substantially more risk than use of other available substitutes.

And EPA in the same document on page 30159 in response to another comment notes further:

> EPA agrees that a recommended AEL from EPA does not provide the same level of protection as an enforceable standard from OSHA..

With regard to the assertion that the proposed PEL of 5 ppm lacked stakeholder input, a special public advisory meeting was held by the Division on May 18, 2005 on the PEL of 1 ppm recommended by the Airborne Contaminants Advisory Committee and the commenter and another commenter in this rulemaking from Albemarle Chemical both attended and provided comments, several of which are referred to in the Initial Statement of Reasons. The proposed PEL being 5 ppm rather than the 1 ppm PEL originally recommended by the Committee reflects, in part, information the commenters provided from the opportunity for stakeholder input provided by the May 18, 2005 meeting.

Richard Morford asserts that the Board did not consider all of the relevant and latest scientific information available in developing the PEL proposed for 1-bromopropane. However, the approach of the Division in developing the proposal, consistent with other standard setting agencies, is not to exhaustively review in detail all available scientific literature on a particular substance but rather to review available, preferably peer-reviewed published research, and choose a single study, or set of studies, which are not inconsistent with other major literature which identifies the most sensitive toxic endpoint and provides a basis for determination of an appropriate health-based PEL level. A major factor in this review process is identifying one, or more, peer-reviewed scientific studies which have been identified by an authoritative government

body as being the most pertinent to the goal of identifying the most sensitive endpoint and providing credible data relevant to determining an occupational exposure limit. As detailed in the Initial Statement of Reasons, that was the approach taken to developing the health basis for the proposed PEL for 1-bromopropane, based upon the findings published in the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR) Monograph on the Potential Human Reproductive and Developmental Effects of 1-Bromopropane dated October 2003. While reports of results from individual research studies in animals and humans on the toxicity of 1-bromopropane have been released since the publication of NTP-CERHR Monograph, there has not been a similar review of that research by an authoritative body such as NTP-CERHR, and none of these new reports provides information that would supplant the conclusions of the NTP-CERHR and the study results upon which they are based.

Moreover, with regard to the comment that the proposed PEL for 1-bromopropane of 5 ppm is based on reports that are out of date, include many inaccuracies, and are based on assumptions which have been shown to be wrong in the time period since their publication six years ago, the commenter does not specify the reports, inaccuracies or erroneous assumptions to which he is referring that were used in developing the proposed PEL. In addition, with regard to the timeliness of the research used to derive the proposed PEL, the comment supports a PEL derivation by TERA (Toxicology Excellence for Risk Assessment) funded by Albemarle Corporation and Ameribrom, Inc. This assessment is dated August 2004 and does not contain any primary research results for assessment of 1-bromopropane toxicity in humans or animals dated later than calendar year 2003.

Comment RM4, by electronic mail received March 19, 2009: In Julia Quint's comments at the public hearing, she implied that because 1-bromopropane is related to or "in the same class as" 2-bromopropane and DBCP (dibromochloropropane), its toxicity is the same. Structure activity relationships may be used to assess toxicological effects when little data exists, but is wholly irrelevant when data does exist. For 1-bromopropane, much data exists to show that its toxic effect is different than either 2-bromopropane or DBCP and that it is the least toxic of these substances. Peer reviewed and published reports since 2003 have shown that 1-bromopropane toxicity is unrelated to these other compounds and he can provide these references if requested. This is more than just a simple inaccuracy. The statement is scientifically wrong. This same structure activity relationship analysis underlies many, if not all, of the statements made in the 2003 HESIS report which is the basis of the current PEL proposal for 1-bromopropane. This is a clear example of why the agency must review all of the current toxicological data to get a clear picture of the compound before proposing a PEL.

Response: When Richard Morford in his e-mail refers to the 2003 HESIS report, it appears he is referring to the Health Hazard Alert on 1-bromopropane released in 2003. In that document, HESIS recommended a workplace exposure limit of 1 ppm to protect against reproductive and nerve toxicity. As discussed in the Initial Statement of Reasons, a PEL recommendation of 1 ppm for 1-bromopropane was discussed by the Committee, but the Board chose instead to base its proposal upon the value of 3.3 ppm also discussed by the Committee. The value of 3.3 ppm was based on the point of departure value for reproductive effects recommended by the NTP-CERHR based upon the findings in the WIL Research Laboratory study as discussed in the Initial Statement of Reasons. Contrary to the suggestion of the comment, the Board's assessment of the risk posed by 1-bromopropane and the proposed PEL were not developed based on analogy with 2-bromopropane, DBCP, or any other substances.

Nancy O'Malley, Albemarle Corporation, by letter dated March 17, 2009

Comment NO1: Albemarle believes that assessments of 1-bromopropane toxicity data and extrapolation to workplace exposure recommendations developed by several other groups should be considered in establishing a PEL for 1-bromopropane in California, including that by ICF, Inc. conducted for the U.S. EPA Significant New Alternatives Program, and another by Toxicology Excellence in Risk Assessment (TERA). Both of these assessments used benchmark dose analysis which is a more powerful statistical tool than the more traditional No Observed Adverse Effect Level (NOAEL) approach used by the Board to develop the PEL proposed for 1-bromopropane. Benchmark dose modeling reduces the uncertainty in the estimates of point of departure, thus reducing the need for application of uncertainty corrections.

Response: Nancy O'Malley suggests that a benchmark dose approach to evaluating the toxicity of 1-bromopropane would be superior to the approach used by the NTP-CERHR panel in evaluating the WIL Research study using the NOAEL as the point of departure for determining an occupational exposure limit. She refers to two analyses of toxicity data for 1-bromopropane which used the benchmark dose approach. She asserts that the approaches used in the analyses by ICF used by EPA in its risk assessment to determine an AEL (as discussed above in Comment RM3 of Richard Morford), and by TERA (also noted in Comment RM3 of Richard Morford above), would be better for the health assessment and PEL derivation for 1-bromopropane. However, Nancy O'Malley does not directly establish that the approaches used by ICF and TERA would be significantly superior to the approach taken by the Board in relying upon the NTP-CERHR assessment of the WIL Research results, nor does the comment directly challenge the essential validity of that approach or the PEL recommendation it generated. It is worth noting that in the NTP-CERHR report, the panel did use a benchmark dose approach in analyzing data for another toxicity endpoint where all of the doses led to adverse effects in the test animals and so no NOAEL was established. This illustrates that the NTP panel could have applied a benchmark dose approach in determining a point of departure from the critical endpoint identified in the WIL Research report but chose not to.

Comment NO2: Albemarle Corporation supports a skin notation for 1-bromopropane as the Board has proposed in order to raise awareness of the need to prevent dermal exposure.

Response: The Board thanks Nancy O'Malley for her comment.

Comment NO3: After review of the 1-bromopropane toxicity and exposure data available at the time, the NTP-CERHR panel expressed minimal concern for adverse effects on human reproduction and development "where exposures were intermittent and well-controlled, as in the example of the cold-bath degreaser". The NTP-CERHR Panel expressed serious concern with the upper end of the exposure range associated with poorly controlled spray adhesive applications, and concluded that a large amount of uncertainty remained as to the safety with intermediate levels of exposure. Albemarle agrees with the concerns associated with the exposure scenarios described in the NTP-CERHR report as well controlled and poorly controlled. However, Albemarle disagrees with NTP-CERHR as to the quantification of exposures added to the levels of concern in the final report. The values cited in the final NTP-CERHR report to correspond with cold-bath degreaser applications were sampled by NIOSH from one site with exposure findings of 0.04 to 0.63 ppm as a TWA. The NTP-CERHR panel stated that the NIOSH sampling data could not be representative of exposure levels nationwide. For several years, Albemarle worked with the Environmental Protection Agency to develop toxicity and physicochemical property data for review by the EPA Significant New Alternatives Program (SNAP) for 1-bromopropane. Albemarle developed its 1-bromopropane recommended workplace exposure

level (AEL) of 25 ppm as a time-weighted average based on the toxicity data supplied for the SNAP program.

Response: With the question raised by Nancy O'Malley on the conclusion of the NTP-CERHR report, the Board believes it is important to include in the record of the rulemaking the entire passage from pages 3 and 4 of the NTP-CERHR final monograph (October 2003) to which the comment refers:

> **Are Current Exposures to 1-BP High Enough to Cause Concern?** Possibly. More data are needed to better understand human 1-BP exposure levels and how these exposures vary across the population. There are no data on 1-BP exposure of the general U.S. population but there are some data available on occupational exposures. Based on the occupational exposure data and studies in humans and laboratory animals, the NTP offers the following conclusions:
> **The NTP concurs with the NTP-CERHR Bromopropanes Expert Panel that there is serious concern for reproductive and developmental effects at the upper end of the human occupational exposure range (18-381 ppm).** Additional support for the expert panel's conclusion is found in more recent rodent and limited but consistent human studies showing that exposure to 1-BP can lead to adverse developmental and/or reproductive effects. Such effects are reported in animal studies at exposure levels of 200 ppm or greater.
> **The NTP concurs with the NTP-CERHR Bromopropanes Expert Panel that there is minimal concern for reproductive and developmental effects when humans are exposed at the lower end of the human occupational exposure range (0.04-0.63 ppm).** This exposure range is far below the "No Observed Adverse Effect Concentrations" identified by the expert panel.

In the above statement from the NTP-CERHR monograph, it is important to note that the "upper end of the human occupational exposure range (18-381)," at which NTP concurs with the NTP-CERHR Expert Panel that there is serious concern for reproductive and development effects, in fact overlaps at its low end with the Acceptable Exposure Limit developed by ICF for EPA of 18 ppm, thus, suggesting that the 25 ppm recommended workplace exposure level referred to in the comment is not appropriate as a PEL. The Board does acknowledge the comment, based on air sampling data in the EPA May 30, 2007 Federal Register Notice cited above in Comment RM1 of Richard Morford, that the "lower end of the human occupational exposure range" cited in the NTP-CERHR monograph would appear to be at the very lowest end of the range of likely worker exposures generated by use of solvent cleaning equipment and probably could not form the basis for determination of a PEL that could be reasonably feasible to achieve in California workplaces. The comment notes that the NTP-CERHR Monograph concluded that a large amount of uncertainty remained as to the safety with intermediate levels of exposure between the ranges noted by the NTP-CERHR panel. The proposed PEL of 5 ppm falls in this intermediate range. The very uncertainty which the comment cites as to safety in the range of the proposed PEL of 5 ppm would not be an argument for a higher PEL, especially when the air sampling data discussed in response to Comments RM1 and RM2 of Richard Morford, above, indicate that compliance with a PEL of 5 ppm is highly achievable with solvent cleaning equipment.

Comment NO4: Albemarle believes the discussion in the Initial Statement of Reasons suggests that the NTP-CERHR made a recommendation for an occupational exposure limit in their evaluation of the potential

human reproductive and developmental effects of 1-bromopropane. The NTP-CERHR panel did not make occupational exposure recommendations. The minutes of the Airborne Contaminants Advisory Committee were misquoted. The minutes indicate that Julia Quint stated "the 3.3 ppm is from the NTP NOEL adjusted with uncertainty factors and exposure time corrections." Thus, the 3.3 ppm derivation was not done by the NTP-CERHR. Rather, the no effect level determined by the NTP-CERHR panel for one of the animal studies evaluated was used as the point of departure for applying safety factors and exposure corrections.

Using a single animal study for the point of departure in determining an exposure limit restricts the number to an actual dose level in the study. The actual no effect level will be higher, but because of uncertainty of where it falls, several uncertainty factors will be applied to the number used to calculate an exposure limit. Use of benchmark dose modeling reduces uncertainty, thus allowing smaller uncertainty factors in calculating an exposure limit. Calculations of exposure limits for 1-bromopropane based on benchmark dose modeling have resulted in recommendations of 20 to 25 ppm as detailed in the EPA SNAP process (the ICF assessment) and the report of TERA (Toxicology for Risk Assessment).

Response: With regard to the first part of the comment, the Board believes that the explanation in the Initial Statement of Reasons with regard to the Board's reliance on the NTP-CERHR panel findings in developing the proposed PEL fully explicates how the 3.3 ppm value was determined in the process of developing the PEL proposal. The language of the Initial Statement of Reasons reproduced below on this point does not suggest that the NTP-CERHR panel made a recommendation for an occupational exposure limit as Nancy O'Malley contends:

> The NTP-CERHR assessment, dated October 2003, was based on reproductive system effects in both male and female rats reported in a study by WIL Research Laboratories in 2001 sponsored by the Brominated Solvents Consortium. The value of 3.3 ppm is calculated from the No Observed Adverse Effect Concentration (NOAEC) of 100 ppm in test animals in the WIL Research study, application of an interspecies uncertainty factor of 3.16 (the square root of 10) and an intraspecies uncertainty factor of 10, and adjustment for an 8-hour workday and 5-day workweek.

With regard to the second part of the comment on the benchmark dose approach, as discussed in response to Nancy O'Malley's first comment, above, the commenter does not establish that the benchmark dose approach would necessarily provide a superior result to using as the point of departure the NOAEL cited by the NTP-CERHR panel. In fact, the benchmark dose analyses by ICF and TERA noted by the commenter yielded recommended occupational exposure limits of 20 to 25 ppm which are within the range which the NTP-CERHR report concluded presented serious concern, detailed as follows, and as was discussed in response to Nancy O'Malley's Comment N03 above:

> The NTP concurs with the NTP-CERHR Bromopropanes Expert Panel that there is serious concern for reproductive and developmental effects at the upper end of the human occupational exposure range (18-381 ppm).

Comment NO5: Albemarle is convinced that the proposed PEL would result in severely curtailed usage of 1-bromopropane and resultantly higher operating costs for industry. Their work demonstrates that two of the most commonly recommended alternatives to 1-bromopropane, hydrocarbon and aqueous cleaning systems have significantly higher energy consumption, with 1-bromopropane in dual tanks with a shower consuming 8.4 kWh, hydrocarbon cleaning (triple tanks, heater and vacuum dryer) consuming 18.5 kWh, and aqueous cleaning (quad tanks cleaning machine and heater dryer) consuming 38.3 kWh. Comparable

costs per 10 kilograms of ferrous alloy cleaned (units not provided in comment letter) would be 720 with a 1-bromopropane based solvent, 1,750 with a hydrocarbon solvent, and 4,245 with an aqueous solvent. While it is difficult to predict the cost impact of the proposed PEL of 5 ppm, it is possible to provide information comparing the cost for operating a 1-bromopropane system with the costs associated with some alternative systems. From their work in the industry, it is apparent that the proposed PEL will result in a significant shift from 1-bromopropane to other substitutes with resulting higher operating costs, and substitution to these alternatives may also result in unintended consequences, including using substances with higher energy requirements, thus, increasing carbon dioxide emissions and using substances with higher Global Warming Potential.

Response: As noted in the response to Nancy O'Malley's Comment NO3 above, air sampling data in the EPA Federal Register Notice of May 30, 2007 and also discussed in response to Comments RM1 and RM2 of Richard Morford above, suggests that the proposed PEL of 5 ppm for 1-bromopropane should be highly achievable with solvent cleaning equipment. That same air sampling data supports the conclusion that a PEL of 5 ppm would result in only a small number, if any, of current or potential users of 1-bromopropane in solvent cleaning equipment in California incurring the increased energy costs suggested in the comment.

Rick Perkins, EnviroTech International, by electronic mail dated March 5, 2009

Comment: Rick Perkins states that he currently works for a manufacturer of 1-bromopropane that also manufactures the equipment where 1-bromopropane and other similar solvents are used. He has noticed over the past several years that toxicologists have been using an uncertainty factor much higher than the standard uncertainty factor when comparing animal exposure to human exposure. Specifically, this number should be 3 times; yet often the uncertainty factor that has been used is 10 or greater.

Response: In the Initial Statement of Reasons, the uncertainty factors applied to the cited No Observed Adverse Effect Concentration (NOAEC) for 1-bromopropane were indicated to be 3.16 (square root of 10) for interspecies uncertainty, and 10 for intraspecies uncertainty, for a cumulative uncertainty factor of 30. However, since the time the PEL Advisory Committee for this proposal made its recommendation based upon the risk assessment incorporating these uncertainty factors, revised OEHHA guidelines for noncancer risk assessment were released in 2008. Those guidelines support reversal of the uncertainty factors cited in the Initial Statement of Reasons, ie. use of an interspecies uncertainty factor of 10 and an intraspecies uncertainty factor of 3. This change is a detail which does not result in a change to the overall uncertainty factor of 30 applied to the No Observed Adverse Effects Concentration of 100 ppm recommended by the NTP-CERHR panel as explained above in responses to several comments of Richard Morford and Nancy O'Malley.

Coal (bituminous) dust

Julia Quint, by letter dated March 18, 2009

Comment: Julia Quint opposes the PEL of 0.9 mg/M^3 respirable particulate proposed for coal (bituminous) dust, given its estimated risk of 13 to 17 cases of progressive massive fibrosis (PMF) per 1,000 workers exposed over their working lifetimes. The commenter supports the PEL of 0.1 mg/M^3 initially recommended by the Committee which they calculated could reduce the risk of PMF to 1 case in 1,000

workers, and which she believes is consistent with the recommendations of NIOSH and ACGIH that exposures to coal dust should be controlled to the lowest level achievable. She notes that a 1/1,000 risk level for health damage is still a substantial and significant risk and represents the lowest level of protection for workers in the range of risks, 1/1,000 to less than 1/billion, discussed by the U.S. Supreme Court in the "benzene decision."

Response: See the response to the similar comment of Michael Smith below.

Michael Smith, WorkSafe, and 12 Co-Signers, by letter dated March 19, 2009

Comment: The commenters oppose the proposed PEL of 0.9 mg/M^3 and urge the Board to adopt the PEL recommended by the Committee of 0.1 mg/ M^3 respirable particulate 8-hour TWA. The value of 0.1 represents a linear extrapolation of the risk noted in the ACGIH TLV of progressive massive fibrosis (PMF). The Initial Statement of Reasons notes that the proposed value of 0.9 mg/M^3 is vastly higher than the 1/1,000 excess risk level suggested in the U.S. Supreme Court's "benzene decision," *Industrial Union Dept. , AFL-CIO v. American Petroleum Institute, et al*, 448 U.S. 607, 634 (1980). The Initial Statement of Reasons cites the documentation of the ACGIH TLV that an exposure level of 0.5 mg/M^3 could be associated with an incidence rate of PMF of 13 to 17 per 1000 exposed workers, a level the commenters believe is likely unlawful under the Board's statutory mandate under Labor Code section 144.6. The commenters note that in recognition of the level of risk remaining at 0.9 mg/M^3 both NIOSH and the ACGIH recommend that worker exposures to bituminous coal dust be controlled to the lowest level achievable and that the NIOSH Criteria Document recommends frequent monitoring of worker exposure to coal dust and participation of exposed miners in medical screening and surveillance.

Response: The commenters assert that simple linear extrapolation should be used to derive a PEL for coal dust that will reduce the risk of disease to the maximum suggested to be acceptable in the "benzene decision" of the U.S. Supreme Court. However, as noted in the Initial Statement of Reasons, the ACGIH TLV documentation presents data to suggest that the risk of disease from exposure to coal dust may in fact not decline linearly between exposure levels of 1.0 mg/M^3 and 0.5 mg/M^3. The commenters have not provided any basis for discounting this previously stated basis for setting the PEL at 0.9 mg/M^3 and therefore, the Board declines to modify the proposal.

Cyclonite; RDX, cyclotrimethylenetrinitramine

Julia Quint, by letter dated March 18, 2009

Comment: Julia Quint supports the proposed PEL for cyclonite of 0.07 mg/M^3 8-hour TWA and details how the value was reached using a quantitative risk assessment approach. She comments that the ACGIH TLV of 0.5 mg/M^3 for this substance does not have a clear scientific basis or rationale, and the value was not derived using quantitative risk analysis.

Response: The Board thanks Julia Quint for her participation in this rulemaking process.

Michael Smith, WorkSafe, and 12 Co-Signers, by letter dated March 19, 2009

Comment: The commenters support the proposed PEL for cyclonite of 0.07 mg/M^3. The commenters applaud the application of quantitative risk assessment by the Committee and Division staff in recommending and proposing this PEL.

Response: The Board thanks the commenters for their participation in this rulemaking process.

1,4 Dioxane

Julia Quint, by letter dated March 18, 2009

Comment: Julia Quint supports the proposed PEL of 0.28 ppm 8-hour TWA for p-dioxane. She states that the cancer risk at the proposed PEL would be 1 excess cancer per 1,000 exposed workers. She states that the value of 0.28 ppm was derived using standard quantitative risk assessment methods employed by other government agencies, i.e. OSHA, EPA, and OEHHA, and is based on OEHHA's published cancer potency data for dioxane. The commenter cites federal OSHA's regulation on identification, classification, and regulation of carcinogens (29 CFR 1990.143) noting that:

> "positive animal studies (one or more experimental studies in one or more mammalian species) are qualitative inference of carcinogenic hazard to workers. Positive results will be used for qualitative identification of potential occupational carcinogens even when non-positive human and animal studies exist."

Julia Quint asserts that water-based products and other safer substitutes are available for p-dioxane for the many solvent applications in which it is used. She also noted that the ACGIH TLV for dioxane is not based on preventing cancer and was not derived using quantitative risk analysis, and that if a TLV were to be derived using such methods but based on non-cancer effects (liver and kidney), a TLV of 4 (rather than 20) would result (based on a no observed adverse effect level (NOAEL) of 111 ppm from a 2-year chronic exposure study in rats identified in the TLV Documentation and used by OEHHA in determining its chronic reference exposure level (cREL) for p-dioxane). She said a value of 4 would be derived by dividing the NOAEL of 111 by uncertainty factors of 10 for interspecies variability and 3 for intraspecies variability.

Response: The Board thanks Julia Quint for her participation in this rulemaking process.

Michael Smith, WorkSafe, and 12 Co-Signers, by letter dated March 19, 2009

Comment: The commenters support the PEL proposed for p-dioxane as recommended by the Committee based upon the cancer unit risk value developed by OEHHA under the authority of Proposition 65. The comment also notes that p-dioxane is the subject of a just-released report by the Environmental Working Group entitled No More Toxic Tub: Getting Contaminants Out of Children's Bath and Personal Products. The commenters note that the report cites classification of p-dioxane by the US Environmental Protection Agency (EPA) as a "probable human carcinogen."

Response: The Board thanks the commenters for their participation in this rulemaking process.

Osei Siriboe, UOP LLC-A Honeywell Company, by letter dated March 19, 2009

Comment: UOP is currently in compliance with all applicable requirements for occupational exposures to 1,4-dioxane and regularly conducts exposure assessments to ensure that it remains in compliance. UOP operations with 1,4-dioxane consist of short duration mixing operations with employee exposures below the current PEL but during which employees wear a loose-fitting powered air-purifying respirator for additional protection, and a casting operation with employee exposures well below the current PEL but not below the proposed PEL revision. They expect a project to achieve compliance with the proposed PEL in the mixing operations would take until April 2010, while in the casting operation they would need until December 2010.

With the proposed substantial reductions in the PEL for 1,4-dioxane, UOP would no longer be in compliance and it would take substantial time, capital investment, and operational changes before UOP could return to compliance. Nonetheless, as part of UOP's commitment to worker health and safety, UOP does not oppose the proposed PEL for 1,4-dioxane. However, UOP requests a two-step delay in the effective date of the proposed PEL to provide the time to identify, purchase, and install cost-effective equipment and procedures. The delay UOP requests is 10 ppm with an effective date of six months after adoption, and 2.5 ppm with an effective date of 18 months after adoption. This delayed implementation of the PEL revisions will ensure that UOP and other businesses have the time needed to come into compliance in a reasonable and cost-effective manner.

Response: This comment letter contains contradictory statements in not opposing the proposed PEL of 0.28 ppm, but at the same time requesting a delay in its implementation with a final value of 2.5 ppm. Assuming the commenter is requesting modification of the PEL to a value of 2.5 ppm with an 18 month delay in implementation, it does not provide specific information supporting the request such as air sampling results for the operations it discusses or risk assessment data responding to that provided by the Board in the Initial Statement of Reasons. In the absence of more specific and detailed information as to why the commenter believes the proposed PEL should be increased by a factor of almost 10 fold, the Board declines to make the change apparently being requested. Recognizing that the comment could have been misinterpreted, Division staff contacted by telephone the site Health and Safety Manager indicated in the commenter's letter, to make sure that the comment was properly understood as summarized above. The Health and Safety Manager indicated that the comment was properly understood, as summarized above, and that no additional clarification of the comment was planned.

Therefore, the Board declines to extend the implementation date to18-months as the commenter's current use of respirators can be expanded within the normal 30-day effective date. Such short-term use of respirators is allowed under existing Section 5141 as a temporary method of compliance while engineering controls are implemented by the expected 2010 dates.

Glyoxal, 1,2-ethanedione

Julia Quint, by letter dated March 18, 2009

Comment: Julia Quint opposes the proposed PEL of 0.1 mg/M^3 8-hour TWA for glyoxal. She notes that the proposed PEL, which is the same as the ACGIH TLV, was not derived using quantitative risk analysis

that would be consistent with methods used by OSHA, EPA and OEHHA, but rather was derived by ACGIH using a "safety factor" of only 4 applied to the NOAEL of 0.4 mg/M^3 from a rat study which found squamous cell metaplasia. The commenter states that adopting the proposed PEL would be unprotective of worker health and is based in part on unwarranted speculation from a glyoxal manufacturer that the PEL of 0.01 mg/M^3 recommended by the Committee would increase the use of formaldehyde. She notes that the significant regulatory burden associated with the comprehensive standard for formaldehyde would not make that chemical a likely substitute for glyoxal. The commenter notes that the Committee recommendation of 0.01 mg/M^3 was appropriately derived by applying to the NOAEL of 0.4 mg/M^3 an interspecies uncertainty factor of 10 and an intraspecies uncertainty factor of 3, and as a result this PEL will assure that workers exposed to glyoxal over a working lifetime will not suffer material impairment of health from squamous cell metaplasia of the larynx and other adverse health effects.

Response: The report of the single animal inhalation study on this substance conducted by an industrial company was available only through a secondary source (BG Chemie: Toxicological Evaluation, Vol. 12. Springer, New York (1998)). In that study, which was the basis of the ACGIH TLV, in a 29-day study using Wistar rats, the book reference states results showed: "minimum squamous metaplasia of the epiglottal epithelium in the larynx that was accompanied by a minimum submucous lymphoid cell infiltration." This effect was seen at exposure levels of 10 and 2 mg/M^3 , but not at a level of 0.4 mg/M^3. However, the Committee expressed concern that the exposure groups consisted of only 10 animals at each dose level. In light of the relative paucity of data on this substance that was available to the Committee, the Board believes the originally proposed value of 0.1 mg/M^3 is appropriate in this rulemaking. Although the Board is concerned with the positive findings for genotoxicity and mutagencity on this substance noted in the Committee's discussion and the TLV documentation, it also notes that with adoption of a PEL for glyoxal California is still likely to be the only state in the nation with a PEL for this substance.

Michael Smith, WorkSafe, and 12 Co-Signers, by letter dated March 19, 2009

Comment: The commenters oppose the proposed PEL of 0.1 mg/M^3 as an 8-hour TWA which is the same as the ACGIH TLV. The commenters recommend a PEL of 0.01 mg/M^3 derived by applying standard uncertainty factors to the no observed adverse effect level (NOAEL) of 0.4 mg/M^3 based upon a well-conducted study for squamous cell metaplasia in rat larynxes. This was the PEL recommended by the Committee.

Response: See the response to Julia Quint's comment, above.

Methyl n-butyl ketone; 2-hexanone

Julia Quint, by letter dated March 18, 2009

Comment: Julia Quint supports the proposed PEL of 1 ppm 8-hour TWA (with a STEL of 10 ppm). She notes that the value of 1 ppm was derived by quantitative risk analysis using methods consistent with those of OSHA, EPA, and OEHHA from a human LOAEL value of 3 ppm for irritation, with application of an uncertainty factor of 3 to account for the use of a LOAEL, rather than NOAEL, value. The commenter notes, consistent with the discussion of the Committee, that a PEL of 1 ppm should also be protective for developmental toxicity.

Response: The Board thanks Julia Quint for her participation in this rulemaking process.

Michael Smith, WorkSafe, and 12 Co-Signers, by letter dated March 19, 2009

Comment: The commenters support the PEL proposed for methyl n-butyl ketone, including the STEL of 10 ppm (15-minute TWA) and note that in addition to the study cited by the Committee for its recommendation based on testicular atrophy in rats, that methyl n-butyl ketone can pose a risk of peripheral neuropathy.

Response: The Board thanks the commenters for their participation in this rulemaking process.

Methyl vinyl ketone

Michael Smith, WorkSafe, and 12 Co-Signers, by letter dated March 19, 2009

Comment: The commenters support, with some hesitation, the PEL proposed for methyl vinyl ketone. The commenters note that the PEL proposed, based on the recommendation of the Committee, did not apply an uncertainty factor to account for the fact that the study cited as the basis for the recommendation did not identify a no observed adverse effect level (NOAEL), but rather only a LOAEL, for which an additional uncertainty factor of 10 should have been applied, along with an uncertainty factor of 3 for intraspecies uncertainty, leading to a PEL of 0.0017 ppm.

Response: The commenters are correct that 0.5 ppm in air was the lowest dose to which rats were exposed in the 13-week Morgan study on which the PEL is proposed to be based, and hyperplasia of the respiratory epithelium was observed with this level of exposure. However, there are a number of factors that weigh against application of a LOAEL to NOAEL uncertainty factor as suggested by the commenters. Most notable is the fact that the PEL being proposed is a ceiling limit not to be exceeded for any length of time. This reflects the intent of the PEL to protect against respiratory irritation. By contrast, the 13-week Morgan study of effects in rats involved an exposure regime of 6 hours per day, 5 days per week for 13 weeks. Additionally, Morgan conducted a 2-week study which involved exposures of 6 hours per day, 5 days per week, for a total of 12 exposure periods. In the 2-week study in rats, a NOAEL of 2 ppm was identified for effects on the rat lung. Since the primary use or occurrence of this substance appears to be as a process intermediate and chemical feedstock, and the fact that it is extremely irritating to the respiratory system even at low concentrations, the Board does not expect that workers would have regular ongoing exposure to methyl vinyl ketone as they might an industrial solvent. For all of these reasons, the Board believes that the recommendation of the Committee for the PEL for this substance was appropriate and declines to accept the suggestion of the comment for revision of the proposal.

Nickel metal and compounds

Hudson Bates, Nickel Producers Environmental Research Association (NiPERA), at the March 19, 2009 public hearing

Comment: Hudson Bates spoke in support of the proposed PEL for nickel, stating that it is scientifically justified. He clarified that written comments submitted by NiPERA with regard to regulation of nickel and other constituents of welding fume, were intended to highlight the need for possibly a special separate PEL

for welding fume constituents, and not to suggest that the proposed PEL should not be applied to nickel in welding fume. He also noted comments submitted by another party (Donna Sivulka) suggesting additional differentiation of nickel species beyond that specified by the proposed PEL. He said that while the scientific information contained in this Donna Sivulka's comment is accurate, NiPERA did not support further subdivision of the categories of nickel in the current and proposed PEL, but rather supported the PEL as proposed.

Response: The Board thanks Hudson Bates for his support and the support of his organization for the PELs proposed for nickel metal and compounds, as well as his participation in the rulemaking process.

Board Member Jonathan Frisch, at the March 19, 2009 public hearing

Comment: Board Member Frisch said that some written comments on the proposed PEL for nickel indicated it would still lead to excessively high cancer burdens, most notably for nickel metal. Hudson Bates responded that any calculation with regard to nickel metal is an excessive calculation, given the fact that a recent high quality animal study published in the scientific literature demonstrated no carcinogenic effect of metallic nickel up to the maximum tolerated dose, and that available human epidemiology studies are also negative. Board Member Frisch asked Hudson Bates if the animal study on metallic nickel he referred to in his comments was incorporated in the Initial Statement of Reasons for this rulemaking. Hudson Bates responded that, while he was unsure whether it had been included in the ISOR, it was published in peer reviewed scientific literature in December 2008.

Response: The article referred to by Hudson Bates with regard to nickel metal, on which he is listed as a co-author, was provided as an attachment to the comments of Adriana Oller, also of NiPERA. The reference for the article is: Oller AR, Kirkpatrick DT, Radovsky A, Bates HK, Inhalation carcinogenicity study with nickel metal powder in Wistar rats, *Toxicol Appl Pharmacol.* 2008 Dec 1;233(2):262-75. To provide perspective on the article, the authors state:

> Existing animal studies with nickel metal powder included earlier studies in rats, mice, guinea pigs, and hamsters via inhalation (Hueper, 1958; Hueper and Payne, 1962). These studies were all negative for respiratory tumor induction. However, some of these studies had very high toxicity or lacked proper controls. Intratracheal instillation and injection studies (e.g., intramuscular, intraperitone al, subcutaneous, etc.) using metallic nickel powders produced both negative and positive results (Ivankovic et al., 1988; Pott et al., 1987; Muhle et al., 1992; and references cited in IARC,1990 or Sivulka, 2005). Intratracheal instillation studies can give false-positive results if physiological clearance mechanisms are bypassed (Driscoll et al., 2000). Therefore, questions still remained about the intrinsic potential of nickel metal to be carcinogenic via inhalation. It was important for a modern study with appropriate controls and design to be done to critically test the hypothesis that nickel metal powders are not carcinogenic.

This paper was too recent to be included in the evaluation of the Committee, but its findings with respect to cancer risk from nickel metal mirror results of earlier studies noted by the Committee. The authors summarized the results of this study as follows:

> The purpose of this study was to determine whether nickel metal powder was carcinogenic to Wistar rats when administered by inhalation 6 h/day, 5 days/week over a two-year period.

> This treatment did not produce an exposure-related increase in tumors anywhere in the respiratory tract, including the nose.

The authors also note considerations with respect to evaluating the non-cancer effects seen in this study:

> The LOAEL for respiratory effects associated with inhalation exposure to nickel metal powder (MMAD=1.8 μm, GSD=2.4 μm) was 0.1 mg/m3. Before these results are used in a risk assessment, the equivalent deposited doses in the pulmonary region of humans need to be calculated. The aerosols present in the workplace are usually much coarser and polydisperse than those used in experimental inhalation studies in rats; with the respirable size fraction (particles of 10 μm diameter) usually comprising less than 10% of the mass of the aerosol (Werner et al., 1999; Tsai et al., 1995, 1996a,b). Consequently, the differences in particle size distribution need to be considered to estimate human equivalent deposited doses that may be associated with similar respiratory effects.

The Board believes that the recency of this study of nickel metal by NiPERA, and the complexity of the picture with respect to the risks posed by the various forms of nickel, supports a recommendation that the Division, with the assistance of HESIS, continue to maintain surveillance of the scientific literature on this subject and, when it deems it appropriate, bring it into the PEL development process for further consideration.

Adriana Oller, Nickel Producers Environmental Researach Association (NiPERA), by electronic mail dated March 6, 2009

Comment AO1: The proposed PEL values for nickel metal and compounds are consistent with the ACGIH TLVs, adjusted for the fact that they will be measured as "total" airborne particulate rather than as "inhalable" particulate. NiPERA supports the PELs proposed for nickel metal and compounds and the Board's decision to establish separate PELs for each of the four main classes of nickel substances. The separate PELs for nickel metal and compounds reflect the well established scientific fact that different chemical forms of nickel have different toxicological properties and/or potencies. Adopting separate PELs for different forms of nickel also has the benefit of allowing for revision of the standards for each form as more data on hazard or risk assessment become available.

Response: The Board thanks Adriana Oller for her participation in this rulemaking.

Comment AO2: NiPERA recommends the adoption of nickel PELs based on the "inhalable" fraction rather than on the "total dust" fraction as the Board has proposed. Epidemiological and animal studies have demonstrated that the most important adverse effects associated with inhalation exposure to nickel occur in the respiratory tract (nose and lung) and relate in part to the deposition of the inhaled nickel-containing particles in upper and lower areas of the respiratory tract. Therefore, it is important to measure exposures to those particles that can be inhaled and deposited in the nose and the deep lung (inhalable aerosol fraction). Many studies conducted in the late 1970s demonstrated that so called "total dust" samplers failed to collect some of the coarser inhalable particles and did not match the inhalability criterion. This led to the development of personal sampling instrumentation that has higher sampling efficiencies and more closely mirrors the inhalable fraction. Adriana Oller, therefore, recommends the adoption of nickel PELs based on the "inhalable" fraction.

Many studies carried out in the nickel producing and using industries have indicated that nickel exposure levels measured as "inhalable" particulate are approximately twice as high (in terms of mass) as nickel exposures measured in terms of "total" particulate at the same location. Therefore, if the nickel PELs now proposed as "total" aerosol were to be adopted by the Board in the future as "inhalable" PELs, the "total" numerical PEL values should be multiplied by a factor of two to correct for the differences in sampling efficiency between "total" and "inhalable" samplers.

Response: The Board understands and appreciates the suggestion that the PEL for nickel metal and compounds be adopted on the basis of the "inhalable" fraction. However, the Board notes that the TLV which the PEL mirrors was adopted on the basis of "total" nickel particulate, and then converted to "inhalable" values based on a comparison of the aerosol collected by the two methods in two electroplating shops. A major concern of the Board with respect to adopting PELs based on the "inhalable" particulate fraction is the increased expense and difficulty of conducting sampling. The inhalable particulate size selectors cost anywhere from one hundred to several hundred dollars each, one must be used with each sample collected, and arrangement must be made ahead of the sampling date to obtain from an industrial hygiene laboratory pre-loaded filter cassettes specific to each model of inhalable size selector. By contrast, sampling for "total" particulate requires only having on hand non-expired mixed cellulose ester filters in plastic cassettes. Especially, as in the case of nickel where the PEL is based in large part on "total" particulate sampling data, and is for a substance such as nickel to which many employees may be exposed, the Board does not believe that the possible greater correlation of the sampling method with the particular point of greatest concern in the respiratory tract outweighs the additional barrier to ease of conduct of air sampling that such a change would represent.

Comment AO3: Scientific reviews of the health effects associated with welding indicate that the effects of welding are not simply the sum of the effects of the individual substances in the mixed exposure (Cross *et al.*,1999; Sivulka, 2005). NiPERA and the Nickel Institute believe that the process of welding should be considered separately for purposes of hazard assessment and for setting occupational exposure limits. IARC (1990) has concluded that the welding process is possibly carcinogenic to humans (Group 2B), and in the EU, the Risk Reduction Strategy Group (2007) concluded that welding should be considered as a candidate for process-oriented risk assessment and risk management. Such a risk assessment would lead to risk reduction measures addressing all relevant aspects of the process, rather than only those aspects related to the presence of one particular substance.

Response: The Board appreciates Adriana Oller bringing to its attention and supporting the concept of consideration of a separate process-oriented approach to the health hazards of welding fume. However, the comment relates to the existing PEL for welding fume which is not part of this rulemaking. Therefore, the Board declines to make any changes to the nickel PEL proposal in response to this comment. However, the Division will take the comment under consideration for a future advisory committee and rulemaking if appropriate.

Rick Kreutzer, California Department of Public Health, by letter dated March 16, 2009

Comment: On July 17, 2007, HESIS recommended to the Division a health-based PEL for nickel and all nickel compounds of 0.019 mg/M^3. This recommendation was derived using a methodology developed by OEHHA and HESIS that uses cancer unit risk values as described in the report produced for HESIS by OEHHA entitled *Occupational Health Hazard Risk Assessment Project for California* (December 2007). With regard to identified carcinogens being considered for regulation, Rick Kreutzer noted that, in most

cases, the Board proposes adopting PELs calculated in a manner consistent the approach described in the OEHHA report. However, in the case of nickel, the PELs being proposed of 0.1 and 0.05 mg/M^3 for metallic nickel and insoluble nickel salts respectively exceed the 0.019 mg/M^3 derived using the OEHHA method and would present significant cancer risks to workers exposed to these compounds (i.e., in excess of one estimated excess cancer death per 1,000 workers exposed for a working lifetime). Therefore, Rick Kreutzer recommends that the Standards Board adopt the original HESIS recommendation of 0.019 mg/M^3 for both metallic nickel and insoluble nickel compounds.

Response: The Board is cognizant of concerns and questions regarding the potential carcinogenicity of nickel metal and compounds. For this reason, the Board in the Initial Statement of Reasons for this rulemaking went into detail on the background of these issues, attempting to present the views of the various parties concerned with the risk posed by exposure to nickel and compounds. The Board does not believe at this time that there is sufficient evidence to warrant a PEL for nickel metal based on risk of cancer, although it is proposing a 2-fold reduction in the existing PEL based on the assessment of the ACGIH. The Board notes that the minutes of the Committee discussions on nickel suggested a great deal of difficulty in identifying data to support a PEL for nickel metal based on cancer risk. The Board believes that the most important element of the proposed PEL for nickel and compounds is the proposed 10-fold reduction in the PEL for insoluble nickel compounds to 0.1 mg/M^3 which the ACGIH based on cancer risk. Based on the ACGIH TLV, the Board is also proposing a 2-fold reduction in the existing PEL for soluble nickel compounds bringing it to 0.05 mg/M^3.

Daniel Cunningham, Metal Finishing Associations of Southern California, by letter dated March 19, 2009 and at the March 19, 2009 public hearing

Comment DC1: Daniel Cunningham and his association have reviewed the Initial Statement of Reasons and proposed PELs for nickel and nickel compounds. It appears the proposal is based primarily on the ACGIH Threshold Limit Values. They are pleased that the proposal retains the existing distinctions in nickel species of the existing PELs because they recognize that different nickel compounds will cause different potential health risks. Although they would prefer that the PEL for soluble nickel compounds remain at the current level of 0.1 mg/M^3, they understand the rationale behind the proposal. Daniel Cunningham and his association consider the proposed standard as tough, but something their industry can achieve to maintain effective protection of their workers' health.

Response: The Board thanks Daniel Cunningham and his association for their support for the proposal and participation in this rulemaking process.

Comment DC2: Daniel Cunningham and his association believe the Initial Statement of Reasons for the PEL revisions to nickel metal and compounds should provide clarification with respect to the air sampling method that is to be used to determine employee exposures and thereby compliance with these PELs. It is their impression that the PELs for nickel metal and compounds being proposed, being based on "total" airborne particulate, are the functional equivalent of the ACGIH TLV values based on the "inhalable" fraction of airborne particulate. It is their impression that the reasoning for this difference between the proposed PELs and the ACGIH TLVs is based upon the more ready availability of air sampling equipment for total particulate sampling. They are concerned that, since it appears the proposed PELs for nickel metal and compounds are based upon the currently approved NIOSH air sampling and analytical methods for total particulate, any future change of the NIOSH methodology could alter the direct correlation of the proposed PELs with their ACGIH counterparts. They have the same concern with respect to speciation. Daniel

Cunningham and his association would like to have this point addressed so that they can properly conduct air sampling, in relation to the nickel PELs, in their industry.

Response: As explained above in response to Comment AO2 of Adriana Oller, Daniel Cunningham is correct that the PELs proposed by the Board to be based on the "total" airborne particulate fraction are, according to ACGIH, the functional equivalent of the ACGIH TLV values based on the "inhalable" fraction of airborne particulate. The Board understands the concern of the commenter with respect to changes in air sampling methods in the future, but believes that a measure of reassurance can be taken from the fact that at the present time it does not appear that federal OSHA is considering modification of its PELs for nickel metal and compounds to be based on the "inhalable" particulate fraction. If in the future, as the commenter suggest, NIOSH were to modify its recommended air sampling method applicable to nickel metal and compounds to the "inhalable" fraction, the regulated public could rely on the applicable federal OSHA sampling method as the basis for continuing to measure airborne exposures based on the "total" particulate fraction. If federal OSHA, at some point, were to adopt PELs for nickel metal and compounds based on the "inhalable" fraction, then at that point the Board would probably do the same in order to maintain its standards as being "at least as effective as" their federal OSHA equivalent. But again, the Board has not seen any concrete indications of federal OSHA considering moving in this direction.

Julia Quint, by letter dated March 18, 2009

Comment: Julia Quint opposes the four PELs proposed for nickel metal and compounds on the basis that none of them adequately protects against the risk of developing cancer. The commenter supports the PEL of 0.02 mg/M^3 8-hour TWA which the Committee recommended for total particulate metal for nickel metal and all nickel compounds. The commenter notes that nickel metal and nickel compounds are identified as carcinogens by NIOSH, NTP, and IARC, and by the State of California on the Proposition 65 list, while in contrast the ACGIH classifies only nickel subsulfide and insoluble nickel compounds as being confirmed human carcinogens. Julia Quint believes that the cancer basis for the PELs for nickel conforms to the federal OSHA regulation pertaining to the identification, classification, and regulation of carcinogens (29 CFR 1990.143) and that the PEL of 0.02 mg/M^3 reduces the risk of cancer to 1/1,000, which, although it is the protection goal for OSHA and Cal/OSHA still represents a significant and substantial health risk for workers. The proposal in the Initial Statement of Reasons to adopt the PELs proposed on an interim basis will further delay adoption of a health protective PEL for nickel.

Response: See the response to the comment of WorkSafe, below.

Michael Smith, WorkSafe, and 12 Co-Signers, by letter dated March 19, 2009

Comment: The commenters write in opposition to the PELs proposed for nickel compounds and supported the recommendation of the Committee of a single PEL for all nickel compounds of 0.02 mg/M^3 8-hour TWA, expressed as elemental nickel. The commenters note that the value of 0.02 is based on the cancer Unit Risk Values for nickel and its compounds generated by OEHHA. The commenters also support the benefit of a single standard for nickel not just based on simplicity and convenience but also because it parallels the effects of nickel and its compounds in the human body, noting the 11th Report on Carcinogens that was discussed in the Initial Statement of Reasons. The commenters also note that NIOSH in its 1977 Criteria Document for nickel proposed a Recommended Exposure Level of 0.015 mg/M^3 as an 8-hour TWA. The commenters note that based upon the cancer Unit Risk Value calculated by OEHHA translating the PEL proposed for metallic nickel into a cancer risk of 51/1,000 workers exposed. The commenters

suggest that by not utilizing the OEHHA information available, the proposed PEL simply ignores the most relevant scientific analyses. The commenters also note that a single PEL for all nickel compounds is the most appropriate given that most workplace chemical exposures are to mixtures rather to individual compounds, or in this case certain groups of nickel compounds, as are proposed to be continued with lowering of the existing separate PELs for nickel metal, soluble nickel compounds, insoluble nickel compounds, and nickel subsulfide.

The commenters conclude by urging the Board not to send the PEL for nickel back to the advisory process for further consideration beyond the values contained in the current proposal as is suggested as a possible means to address the problem in the Initial Statement of Reasons.

Response: Given the cancer risk discussed in the Initial Statement of Reasons for this set of substances, the Board shares the concerns of the commenters that the PELs for these substances be appropriately protective for the risk that they present. At the heart of the comment with respect to the PELs for nickel metals and compounds is the question of whether there should be a single PEL for all of these substances even though it is widely recognized that they likely pose significantly different levels of risk for cancer. As was noted in the Initial Statement of Reasons, both the International Agency for Research on Cancer (IARC) and the National Toxicology Program (NTP) recognize that there is significantly less evidence for the carcinogenicity of nickel metal in humans than for the soluble and insoluble forms.

The Board believes it is important to note that although the Committee in the end recommended a single PEL for metallic nickel and compounds, it struggled over the course of two extended discussions with the issue of the differences in evidence for carcinogenicity of nickel metal and nickel compounds. However, in the end the Committee concluded that a single exposure limit was best because there was no basis for setting a limit for the metal that was different from that for the other compounds. In developing the proposed PEL for nickel the Division, to whom the Committee's advice went, after obtaining comments at the May 18, 2005 meeting, including those of NiPERA, disagreed with the approach taken by the Committee in the face of its conclusion regarding the different cancer risks apparently posed by the different forms of nickel. Instead, the Division recommended, and the Board proposed adoption of, the ACGIH TLV and its differentiation scheme, most notably, of nickel metal from soluble and insoluble nickel compounds. The Board concurs with the recommendation of the Division that the PEL for nickel, at least for the time being, should be adopted at the level of the ACGIH TLV, with the differentiation of metal, soluble compounds, insoluble compounds and nickel subsulfide.

Donna J. Sivulka, Environmental Regulatory Consultant, on behalf of certain former members of the now disbanded High Nickel Alloy Health and Safety Group, by letter dated March 17, 2009

Comment: There is no clear evidence that oxidic nickel devoid of copper is carcinogenic in humans. To the contrary, where oxidic nickel—free of copper—is present in workplace settings where nickel subsulfide is absent, epidemiological studies have overwhelmingly and consistently shown no evidence of respiratory cancer. The evidence from studies of nickel alloy workers and inhalation studies in animals suggests that a PEL for oxidic nickel devoid of copper need not be set lower than 0.5 mg/M^3 "total" nickel. A PEL set at that level would protect against both malignant and non-malignant respiratory effects.

Response: The Board finds the requested modification of the PEL for nickel and nickel compounds, as well as the detailed information provided in the comment, to be interesting but not sufficiently compelling to warrant revision of the proposal, particularly in light of comments received that there should be a single

PEL for nickel metal and the fact that the ACGIH TLV does not reflect the further speciation that the comment suggests. Furthermore, the Board is concerned with information provided in the comment letter suggesting a need for caution:

> Additional insight into the carcinogenic potential of copper free oxidic nickel can also be gleaned from a chronic bioassay conducted by NTP on rats administered a high temperature nickel oxide that did not contain copper (NTP, 1996a). This study was completed after the results of the ICNCM study had been published. This study showed "some" evidence of increased lung cancer rates (combined alveolar adenomas or carcinomas) in both sexes of rats administered nickel oxide at the middle dose tested (1mg Ni/m3). The lowest dose tested (0.5 mg Ni/m3) showed no evidence of increased risks of lung cancer in either sex, and the highest dose tested (2.0 mg Ni/m3) showed evidence of increased risks only in female rats. In contrast, nickel subsulfide showed "clear" evidence of increased risks at the lowest dose tested (0.11 mg Ni/m3), as well as at all subsequent higher doses (NTP, 1996b). This suggests that while a copper-free nickel oxide, theoretically, has the potential to cause cancer, it is not particularly potent, and as noted above, the evidence for it to do so in humans has not been shown in nickel alloy workers or certain other nickel-using industry workers; nor is there compelling evidence that is has caused increased risks of cancers in "no- or low-risk" workers processing sulfide containing ores at Clydach.

The finding of increased risk of cancer in female rats cited by the comment suggests a need for caution in following the recommendation of the comment for a PEL for copper-free oxidic nickel equal to no less than that for nickel metal. The Board notes also that at the public hearing on March 19, 2009, Hudson Bates of the Nickel Producers Environmental Research Association (NiPERA), expressed agreement with the information presented in the comment but said that NiPERA does not support further differentiation of the PELs for nickel compounds beyond that in the proposal based upon the ACGIH TLV. Hudson Bates' statement reflects the written comments submitted by Adriana Oller of NiPERA, pointing out the scientific paper authored by the commenter on the central subject of her request, but not commenting on a modification of the proposed PEL to incorporate it.

Ozone

Julia Quint, by letter dated March 18, 2009

Comment: Julia Quint supports the proposed PEL of 0.1 ppm Ceiling for ozone. The proposed PEL has a scientific basis and will protect workers exposed to ozone from decrements in lung function, a material impairment of health. In addition to improving protection for workers, having one PEL for ozone instead of different PELs based on work activity (recommended by the ACGIH) should ease the compliance burden for employers and facilitate Cal/OSHA enforcement of the PEL.

Response: The Board is withdrawing the proposed amendment of the existing PEL for ozone because federal OSHA has determined that the PEL Ceiling value as proposed, with a footnote allowing for exclusion of ambient exposure levels, would not be at least as effective as the federal OSHA PEL for ozone consisting of just the existing California 8-hour time-weighted average value of 1 ppm. Federal OSHA has indicated that effectiveness, equivalent to the federal OSHA PEL, could not be obtained by simply restoring the

existing 8-hour time-weighted average PEL value which had been proposed to be deleted, and enforcing it along with the proposed Ceiling value modified by the footnote to allow for exclusion of ambient levels of ozone. Therefore, the Board is withdrawing the proposed amendment of the existing PEL for ozone.

Michael Smith, WorkSafe, and 12 Co-Signers, by letter dated March 19, 2009

Comment: The commenters support the proposed PEL which was recommended by the Committee based on the study of Horstmann et al. as indicated in the Initial Statement of Reasons. The commenters believe that, as recognized by the Committee, the activity –based ACGIH TLV for ozone is not practical as a regulation and would invite confusion on the part of employers to which it would apply.

Response: The Board thanks the commenters for their participation in this rulemaking process. See the response to Julia Quint's comment above on ozone for an explanation of why the Board is withdrawing the proposed amendment of the existing PEL for ozone.

Refractory ceramic fiber (RCF)

Dean Venturin, Refractory Ceramic Fibers Coalition (RCFC), at the March 19, 2009 public hearing

Comment: Dean Venturin expressed support for a PEL for refractory ceramic fiber (RCF) of 0.5 f/cc, rather than the 0.2 f/cc proposed. He noted that the Coalition had been operating a product stewardship program for RCF for the last 20 years, including assistance to customers and end users, to help them with control and reduction of fiber exposures. He noted the following items in his written comments summarized and responded to below:

1. A published study of 17 years of air monitoring results for RCF shows that exposures are currently very low, having been decreasing over time.

2. The phase contrast microscopy (PCM) method of air sample analysis can see only about 14% of the asbestos fibers in an air sample because of their dimensions and limitations of PCM to see fibers of a thickness below a certain dimension, whereas, RCF with few thin fibers not being visible the method sees and counts almost 100% of airborne RCF fibers. He said this meant that the PEL for RCF would effectively be much more stringent than the PEL for asbestos, a known human carcinogen.

3. RCF has been extensively studied and has not been known to cause human disease.

Board Member Frisch asked Dean Venturin if the time-weighted average exposure diagram in his written comments is correct since it shows exposures being between 0.1 and 0.2 f/cc. Dean Venturin said in his response that the figure in his letter was correct with regard to exposures, but it does not mean that all exposures can currently be controlled to 0.2 f/cc, or the 0.15 f/cc that would be required for an employer to be assured of that. He also reiterated his comment regarding the limits of phase contrast microscopy, that a PEL of 0.5 f/cc for RCF was still lower, really, than the PEL for asbestos of 0.1 f/cc.

Response: See the responses below to the written comments of Dean Venturin and Kurt Blase.

Tom Walters, Thermal Ceramics, at the March 19, 2009 public hearing

Comment: Tom Walters spoke in support of Dean Venturin's comments. He said studies on RCF in rats and mice in the early 1980s had suggested potential harmful effects. He said that these studies were started at approximately the same time as a long term medical surveillance study on RCF workers which began in 1987 at the University of Cincinnati in conjunction with RCF manufacturers' medical surveillance program. He said the Cincinnati study has continued for more than 20 years, including respiratory questionnaires, lung function tests, chest x-rays, and assessment of worker mortality. He said, to date, the results of the worker study has shown no excess mortality, no statistically significant increases in interstitial findings, and no mesotheliomas. He said that through 1996, some elevated level of pleural plaques had been found, but that with lower exposure levels since then they have not been found at an elevated rate. He said that the Cincinnati study is continuing and that another report is soon to be published. He said that although human disease from RCF has not been documented, a risk assessment using animal data was conducted in 1998 showing levels of risk as discussed in Dean Venturin's comments which indicate that 0.5 f/cc is appropriate as a PEL.

Board Member Frisch asked Tom Walters if the Cincinnati study was the only epidemiologic study of RCF. Tom Walters responded that it was the only study in North America, but that a study had also been conducted in Europe and had reached similar conclusions. Tom Walters noted that the European study was not ongoing like the Cincinnati study. Board Member Frisch asked him if these studies had been submitted as part of the Division's advisory process for the proposal, and he said they had.

Response: See the responses below to Dean Venturin's written comments which address the points made by Tom Walters.

Bill Kelly, Unifrax, at the March 19, 2009 public hearing

Comment: Bill Kelly said that the proposed PEL of 0.2 f/cc is too stringent. He said the RCFC had provided technical and economic impact feasibility information to the Division but that it was discounted to a substantial degree in the Initial Statement of Reasons. He said that RCFC had submitted additional information in Dean Venturin's written comments showing that the cost of meeting the proposed PEL would be approximately $4,000 per worker per year.

Bill Kelly said that epidemiology studies of RCF had shown there is no disease associated with RCF exposure. He said that given the limitations of phase contrast microscopy and the fiber size distributions of asbestos and RCF, the proposed PEL of 0.5 f/cc is about three and one-half times as stringent as the PEL for asbestos, a known carcinogen. He said that HESIS, taking into account feasibility and risk analysis, had recommended a PEL of 0.5 f/cc. Bill Kelly said that RCF has been in use since the 1940s and that current data demonstrates that approximately 85% of exposures, including among users, workers, and manufacturers are below 0.5 f/cc. He said that RCF is used carefully around the world and that there has been no evidence of long-term disease, and that based on that a PEL of 0.5 f/cc appears to be technically and economically feasible.

Board Member Frisch commented that the exposure study presented in RCFC's written comments indicates that most employers are already using the 0.2 f/cc standard. Bill Kelly stated that 85% of the current exposures are below 0.5 f/cc among manufacturers and users. If a PEL of 0.2 f/cc was adopted, those manufacturers and users,

in order to assure that they were at or below that level, would have to control to a much lower level such as 0.1 f/cc. He said there are not workplaces operating at that level currently.

Board Member Frisch asked Bill Kelly what percentages of exposures to RCF are below 0.2 f/cc currently. Bill Kelly responded that that information can be found in the written comments of Dean Venturin.

Response: Comments similar to these were also made in the letters of Dean Venturin and Kurt Blase representing the Refractory Ceramic Fibers Coalition. Please see the responses to the comments made in these letters, below.

The Standards Board would like to note that it applauds the RCF industry's support of research on the potential hazards of RCF, and the product stewardship effort of RCF producers. The RCF industry has collected exposure data under a quality assurance project plan designed in conjunction with Federal EPA. These data have been shared with the Division as well as U.S. Department of Labor and other interested regulators. These data show that, with the help of RCF producers, users have achieved average TWA exposures well below the voluntary limit of 0.5 f/cc and in most circumstances at or below the proposed PEL of 0.2 f/cc. Therefore, in light of the totality of evidence cited by ACGIH and NIOSH on the potential for RCF to cause or contribute to respiratory disease, the Standards Board believes that a PEL for refractory ceramic fiber of 0.2 f/cc is feasible and necessary to protect workers.

The Standards Board appreciates the concerns raised by RCFC that, although measurements of airborne exposure to RCF for some operations have averaged below 0.2 fibers/cc, the variability of the results indicates that employers cannot assume that a single sample on any particular day will always indicate an 8-hour TWA exposure that does not exceed this level. These employers will have the option of supplementing engineering controls with respirator use or finding ways to improve engineering controls.

The problem of variability in assessments of worker exposures has been a subject of active research and controversy since the 1970's. The comments made by RCFC have highlighted this issue. The Division has determined that the time has come to confront the manner in which current enforcement approaches are affected by variability in exposure assessment and has expressed a commitment to begin discussion of this issue publicly.

However, a third option appears warranted in connection with the permissible exposure limit for RCF. In a workplace where it appears all feasible engineering controls for RCF have been implemented but the employer is not statistically certain that an individual sample result will never exceed 0.2 fibers/cc: In recognition of the commonly encountered high variability of airborne personal sampling results and the narrow interpretive value of a single sample with respect to overall employee exposure in a work environment, the Division has indicated that it will explore utilization of an enforcement strategy designed to promote (1) robust and proactive sampling by employers before they are targeted for enforcement inspections and (2) better characterization of mean exposures employees are experiencing in their work.

This approach would recognize that robust sampling strategies based on statistically driven, multiple-sample approaches and carried out in accordance with sound industrial hygiene practice and documentation, can allow for the drawing of significantly more competent and reliable conclusions about probable 8-hour TWA exposures than are possible with single-sample strategies. These types of sampling strategies are the subject of discussion in recent scientific literature.

In addition to promoting greater employer attention to making accurate conclusions about employee exposure, this kind of sampling and analysis would be better calculated to quantify the exposure environment in terms of the "working lifetime" principle embodied in Labor Code Section 144.6. One enforcement option consistent with this principle could allow an employer to demonstrate that, although individual samples may exceed 0.2 fibers/cc on occasion, it has reliably characterized 8-hour TWA exposure overall to be below 0.2 fibers/cc for workers in similar exposure scenarios, the Division would accept these results if the enforcing officer's own sampling on a single occasion indicates that the level of 0.5 fibers/cc has not been exceeded. This is not meant in any way to imply that the Division should refrain from using multiple sampling and statistical approaches where it chooses to develop them, but it is meant to promote utilization of the best information available to assess the actual exposure of workers for the purpose of compliance assessment.

Board Member Jonathan Frisch, at the March 19, 2009 public hearing

Comment: Board Member Frisch asked Bob Barish if the Division had "discounted" the cost information provided by RCFC as Bill Kelly had suggested in his oral comment.

Response: Bob Barish said that information obtained from RCFC had been used in the cost assessment as detailed in the ISOR, but that the ISOR cost discussion also spells out where the Division disagreed with the details and, thus, the overall conclusion of RCFC's cost assessment. Bob Barish said it appeared RCFC had made some changes and clarifications in the written comments of Dean Venturin on cost and that the Division would look at this new information and respond to it.

Board Member Jonathan Frisch, at the March 19, 209 public hearing

Comment: Board Member Frisch asked Bob Barish how the advisory committee had considered the human health data for RCF in relation to the animal testing results.

Response: Bob Barish replied that the advisory committee looked at both the human and animal findings in recommending a PEL of 0.1 f/cc, and noted concern with conclusions on the epidemiology and with the assumptions made in the Moolgavkar et al. (1999) risk assessment. He said that the proposed PEL was based on the totality of the information available to the Division on RCF.

Board Member Jonathan Frisch, at the March 19, 2009 public hearing

Comment: Board Member Frisch said that RCFC is making an enormous extrapolation in their written comments when using animal studies to determine safe levels of RCF exposure for humans. He asked that the Final Statement of Reasons provide a clear, detailed explanation for the rationale for the proposed PEL of 0.2 f/cc.

Response: See the responses below to:

1. Julia Quint's oral comment made in response to a question from Board Member Frisch with regard to the quantitative risk assessments for cancer on RCF.
2. Kurt Blase's written comment KB2.
3. Dean Venturin's written comment DV1.

George Alvarez, Thermal Ceramics, at the March 19, 2009 public hearing

Comment: George Alvarez said that the Los Angeles basin is second only to the U.S. Gulf Coast in terms of concentration of petrochemical furnaces, and that each of those built in the last 25 years is designed to be lined with RCF. He said that a PEL of 0.2 f/cc would require every petrochemical furnace lined with RCF to be redesigned and rebuilt for a heavier insulating material since such a PEL would amount to a ban on RCF.

Board Member Frisch said there was no proposal to ban RCF, and he asked for human exposure data to show that a PEL of 0.2 f/cc would necessitate the action that George Alvarez referred to. George Alvarez responded that it would be nearly impossible to repair or reline existing vessels without exceeding exposures of 0.2 f/cc. Board Member Frisch asked why this was the case and George Alvarez responded that in his experience such operations typically generate exposures of 0.5 to 0.8 f/cc, although he noted that wetting of the material, and use of respirators, could reduce the exposures. He said, however, that exposure during installation of RCF are generally above 0.2 f/cc. Board Member Frisch stated that he has difficulty believing that it is not possible to reduce exposure levels. He stated that he does not see an articulate explanation of why it is not feasible. George Alvarez responded that he had not seen an RCF installation with exposures below 0.5 f/cc in his 28 years of working with the material.

Response: See the response to Paul Darnell's similar written comment, by letter dated March 19, 2009.

Julia Quint, at the March 19, 2009 public hearing

Comment: Responding to Bill Kelly's reference to HESIS' suggested PEL of 0.5 f/cc, the commenter said that recommendation was strictly to suggest that the Division evaluate the NIOSH recommendation in the 2006 Criteria Document, but it was not a level recommended by HESIS while she was Chief there. She praised the RCFC's work with NIOSH and its efforts to reduce exposures. She said that in her current role as an individual, she supported the PEL of 0.2 f/cc although she said the risk of disease even at that level was too high. Board Member Frisch asked Julia Quint what the cancer risk of RCF is at 0.2 f/cc. She said she had not calculated it as NIOSH had done in its criteria document, although she offered to do so.

Response: In regard to the question of Board Member Frisch asking what the cancer risk of RCF is at 0.2 f/cc, this information from page 100 of the NIOSH Criteria Document is noteworthy:

> The risk for mesothelioma at the REL of 0.5 f/cm is not known but cannot be discounted. Evidence from epidemiologic studies showed that higher exposures in the past resulted in pleural plaques in workers, indicating that RCFs do reach pleural tissue. Both implantation studies in rats and inhalation studies in hamsters have shown that RCF fibers can cause mesothelioma. Because of limitations in the hamster data, the risk of mesothelioma cannot be quantified. However, the fact that no mesotheliomas been found in workers and that pleural plaques appear to be less likely to occur in workers with lower exposures suggests a lower risk for mesothelioma at the REL.
>
> Because residual risks of cancer (lung cancer and pleural mesothelioma) and irritation may exist at the REL, NIOSH further recommends that all

> reasonable efforts be made to work toward reducing exposures to less than 0.2 f/cm3. At this concentration, the risks of lung cancer are estimated to be 0.03 to 0.47 per 1,000 based on extrapolations of risk models from Sciences International [1998], Moolgavkar et al. [1999], and Yu and Oberdörster [2000].

Furthermore, it is worth noting, that just as the Committee, as detailed in the minutes of its discussion of RCF, expressed concern with what it believed were non-conservative assumptions made in the Moolgavkar et al.(1999) risk assessment, NIOSH with respect to the three risk assessments noted in the quote above from the 2006 Criteria Document for RCF, stated the following on page 88 of that document:

> A common weakness among all three of the risk analyses stems from uncertainty about possible differences in the sensitivity of human lungs to fibers, as compared with rat lungs. The possibility of such a difference is acknowledged in the report by (Moolgavkar et al. [1999], but the effect of this uncertainty on the risk estimates is not explored quantitatively. As an example, Pott et al. [1994] estimated that in the case of asbestos fibers, humans are approximately 200-fold more sensitive than rats, on the basis of fiber concentration in air. Pott et al. [1994] further noted that a crocidolite inhalation study that was negative in the rat resulted in a rat lung fiber concentration that was more than 1,000-fold greater than the fiber concentrations in the lungs of asbestos workers with mesotheliomas.
>
> The lung cancer risk estimates for RCFs derived by Moolgavkar et al. [1999] may also be underestimated for occupationally exposed workers because of several basic assumptions made in the lung tissue dosimetry. Tissue dosimetry modeling in the Moolgavkar et al. [1999] risk assessment is based on the assumption that a worker is exposed to RCFs for 8 hr/day, 5 days/week, 52 weeks/year, from age 20 to 50 [Moolgavkar et al. 1999]. An alternative analysis, in which the assumption was changed to 8 hr/day, 5 days/week, 50 weeks/year from age 20 to 60, was also described but not presented in detail. In both cases, the breathing rate for light work was assumed to be 13.5 liters/minute. Additional information might be gained from assuming an exposure period of 8 hr/day, 5 days/week, 50 weeks/year, from age 20 to 65, with a breathing rate matching the International Commission on Radiological Protection "Reference Man" value for light work, which is 20 liters/minute [ICRP 1994]. In addition, the cumulative excess risk of lung cancer was calculated only through age 70 [Moolgavkar et al. 1999]. This practice may underestimate the lifetime risk of lung cancer in the exposed cohort, since a substantial fraction of the cohort may be expected to survive beyond age 70. The excess risk might also be calculated in a competing-risks framework using actuarial methods until most or all of the cohort is presumed to have died because of competing risks (generally 85 years). Finally, risk estimates derived by Moolgavkar et al. [1999] were based solely on data from studies with rats, ignoring data from studies of hamsters [McConnell et al. 1995]. Because 42% of the hamsters in these studies developed mesotheliomas, using this database for the risk assessment would produce higher estimates of risk than the analysis based on the rat data.

The above NIOSH assessment of several animal based quantitative risk assessments of RCF for lung cancer indicates a need for substantial caution in relying on the values reached from them directly in deciding upon a PEL for RCF, especially since, as the NIOSH Criteria Document notes, they did not

address risk of mesothelioma found in inhalation studies of hamsters. The Board does not believe these risk assessments by themselves are an appropriate basis for determining a PEL for RCF.

Bob D'Amoto, American Safety Institute, at the March 19, 2009 public hearing

Comment: Bob D'Amoto said that he could see no basis for any adverse health effects from refractory ceramic fibers and so he did not see a basis for the need for a PEL as proposed.

Response: As detailed in the Initial and Final Statement of Reasons, and in the NIOSH Criteria Document of 2006 for refractory ceramic fibers that was included as a Document Relied Upon in the Initial Statement of Reasons, the Board believes workplace exposure to refractory ceramic fibers can pose a health risk which warrants development of a Permissible Exposure Limit.

Aileen (Chuca) Meyer, Pillsbury Winthrop Shaw Pittman LLP for Refractory Ceramic Fibers Coalition, by letter dated March 17, 2009

Comment: The commenter introduced the letter of Kurt E. Blase and co-signed by Chuca Meyer.

Response: The comments of this letter are summarized and responded to below. (See the responses to the comments in the letter of Kurt E. Blase, co-signed by Chuca Meyer).

Kurt E. Blase, Blase Law Group, LLC, and Aileen (Chuca) Meyer, Pillsbury Winthrop Shaw Pittman LLP, for Refractory Ceramic Fibers Coalition, by letter dated March 19, 2009

Comment KB1: The Board's proposal rejects the recommendation of HESIS in the California Department of Public Health to adopt a PEL of 0.5 f/cc. The HESIS recommendation was based on the Recommended Exposure Limit (REL) adopted by NIOSH. The NIOSH REL, in turn, is based on the Recommended Exposure Guideline (REG) adopted in the RCF Coalition's Product Stewardship Program (PSP). The PSP, including the REG of 0.5 f/cc has been endorsed by federal OSHA in lieu of adoption of a federal PEL. HESIS noted in recommending a PEL of 0.5 f/cc that it is supported by the results of quantitative risk assessment, whereas the proposed PEL of 0.2 f/cc is not. In a companion report, the Cal/EPA Office of Environmental Health Hazard Assessment (OEHHA) provides additional support for the HESIS recommendation and further notes that the ACGIH TLVs are not risk-based and thus it is not clear what level of protection the TLVs provide.

Response: The commenters are correct that both HESIS and OEHHA have cited the NIOSH REL of 0.5 f/cc as having been based on quantitative risk assessment, and both organizations indicate a preference for setting PELs based on quantitative risk assessment where sufficient data is available to do so effectively. However, staff of both HESIS and OEHHA, have indicated to the Division that neither of their organizations intended their reference to the NIOSH REL of 0.5 f/cc to be viewed as a direct recommendation of that value for a PEL for RCF. This is consistent with the comment summarized above of former HESIS Chief Julia Quint at the public hearing on March 19, 2009. HESIS and OEHHA staff have both indicated to the Division that neither of them have evaluated the NIOSH risk assessment and therefore neither can "recommend" the NIOSH REL 0.5 f/cc as it is asserted by the commenters that they did. Both the HESIS and OEHHA citations of the NIOSH REL for RCF are best understood as being a suggestion to the Division, and the Board, to consider the NIOSH evaluation and REL for RCF because it was based on quantitative risk assessment, these two agencies' preferred approach to risk assessment. Consistent with

this, the Committee, in its deliberations on RCF, did carefully evaluate the Moolgavkar et al. (1999) risk assessment and, as noted above in response to a comment from Board Member Frisch, the Committee was concerned that a number of the assumptions of Moolgavkar et al. (1999) were relatively non-conservative. NIOSH expressed similar reservations in its 2006 Criteria Document.

It is also important to note that the NIOSH REL of 0.5 f/cc is not a stand-alone PEL as is being proposed in this rulemaking, but rather includes specific extensive recommendations for the following to supplement the PEL value:

Exposure monitoring	Hazard communication	Employee training
Engineering controls and work practices		Respiratory protection
Sanitation and hygiene	Medical monitoring	Labeling and posting
Smoking cessation		

Comment KB2: The ACGIH TLV of 0.2 f/cc is not based on risk assessment and provided little scientific support for the 0.2 f/cc value. The TLV is based in large part on the prevention of pleural plaques which is not an appropriate basis for a PEL because OSHA has recognized that pleural plaques are an indication of prior exposure to respirable fibers but do not in themselves constitute "material impairment" of health as that was discussed in OSHA's 1994 Federal Register Final Rule Notice for its current asbestos standard. In that document, OSHA indicated that health effects such as lung function impairment and pleuritc pain would be considered "material impairment" if substantial evidence supports the link to pleural plaques.

Response: It is important to note that while the PEL value of 0.2 f/cc for RCF that the Board is proposing to adopt is the same value as the ACGIH TLV, it is not adopting this value without having done its own evaluation of the TLV and the hazard of RCF. It is further important to note that the Division's PEL Advisory Committee originally recommended a PEL value of 0.1 f/cc based in large part upon the findings of effects on pulmonary function apparently linked to RCF exposure in the study of Lockey et al. (1998), and not the findings of pleural plaques noted by the commenters, and by ACGIH. With respect to the significance of the findings of pleural plaques among RCF workers, the NIOSH Criteria Document for RCF notes the following:

> Evidence of pleural plaques observed in persons with occupational exposures to airborne RCFs is clinically similar to that observed in asbestos-exposed persons after the initial years of their occupational exposures to asbestos [Hourihane et al. 1966; Becklake et al. 1970; Dement et al. 1986]. NIOSH considers the discovery of pleural plaques in U.S. studies of RCF manufacturing workers to be a significant finding because the plaques were correlated with RCF exposure [Lemasters et al. 1994; Lockey et al. 1996].

Contrary to the suggestion of the commenters, pleural plaques were only one of several factors and findings with respect to RCF that led ACGIH to adopt a TLV of 0.2 f/cc. The Board is not persuaded by the comment that the proposed PEL of 0. 2 f/cc is not appropriate.

Comment KB3: Labor Code section 144.6 requires that in setting standards concerning toxic materials or harmful physical agents the Board "…shall adopt that standard which most adequately assures, to the extent feasible, that no employee will suffer material impairment of health or functional capacity…" Given the conclusions of HESIS and OEHHA that the protection provided by the ACGIH TLV cannot be quantified in the absence of risk assessment, section 144.6 prohibits adoption of the TLV as the state standard for RCF. Also, the Board has determined that the proposed PEL for RCF is feasible based in large part on materials

previously submitted by RCFC. However, as explained in the comment letter of Dean Venturin of RCFC, the Board has made critical changes to the RCFC analysis that are not supported by the relevant data. Absent these changes, the record clearly demonstrates that the proposed PEL for RCF is not feasible for RCF users in California, and is yet another reason to abandon the proposal in favor of a PEL of 0.5 f/cc.

Response: See the response to Comment KB1 of Kurt Blase, above, regarding HESIS and OEHHA reference to a PEL value of 0.5 f/cc. See the response to Dean Venturin's written Comments DV5, DV6, and DV 7, below, regarding the cost assessment of the proposed PEL of 0.2 f/cc for RCF.

Comment KB4: The proposed PEL of 0.2 f/cc for RCF is inconsistent with the following requirements of the California Administrative Procedure Act (APA):

- **Least burdensome requirement.** The Board must find that no alternative would be more effective in carrying out the purpose for which the PEL is proposed or would be as effective as and less burdensome to affected private persons. As discussed in the RCFC comments, a final PEL of 0.5 f/cc would be more effective in fulfilling the purposes of the California Labor Code, and also would be less burdensome for RCF users.

- **Business and employment impacts**. A final PEL of 0.5 f/cc would be feasible for businesses in California that use RCF. The proposed PEL of 0.2 f/cc would not be feasible. Adoption of an infeasible PEL for RCF may eliminate jobs or businesses in California for which no suitable substitute is available. Some of the affected businesses may be small businesses.

- **Nonduplication**. A rulemaking agency must state whether a regulation differs from a federal statute or regulation and avoid unnecessary duplication or conflict. While the proposed PEL of 0.2 f/cc would differ from the effective federal standard of 0.5 f/cc, no justification has been provided as required by the California Labor Code.

- **Consistency.** The PEL must be in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law. As discussed above, the proposed PEL is inconsistent with the governing provisions of the California Labor Code. It is also inconsistent with the purposes of the state statutes for control of greenhouse gas emissions**.** If the Board adopts a PEL that discourages or effectively prohibits use of RCF in California, the substantial benefits that RCF provides in energy savings and reduction of greenhouse gas emissions would be lost. Such a result would be inconsistent with the purposes of AB32 as well as the California Labor Code. A PEL of 0.5 f/cc would achieve consistency with the purposes and requirements of both statutes.

- **Necessity**. The Board has not shown by substantial evidence that the proposed PEL is necessary to fulfill the purposes of the California Labor Code.

For all of these reasons, the proposed PEL of 0.2 f/cc would be inconsistent with the requirements of the California APA. The inconsistencies would be cured through adoption of a final PEL of 0.5 f/cc.

Response: The commenters have not provided a detailed basis for their assertions that the proposed standard does not meet the requirements of the APA. By far the greatest number of employees in California being exposed to RCF are in the "furnace related" industry segment as detailed in Dean Venturin's Comment DV5 below, and these employees' exposures are frequently in excess of 0.5 f/cc according to data

attached with Dean Venturin's comment letter (Maxim et al. 2008 paper). Furthermore, page D-61 of 172 in the attachment to the commenter's letter states:

> Because many major removal jobs occur in confined spaces (inside furnaces), and because major removals are infrequent at any given site, engineering controls are generally not applicable.

In the absence of ready availability of effective engineering controls in the "furnace related" industry segment, it appears these employers will generally need to control exposures using respirators, and whether control is to a PEL 0.2 f/cc or a PEL of 0.5 f/cc as is preferred by RCFC, the minimum acceptable type of respirator would be expected to be the same in the vast majority of cases. i.e., a full-facepiece or half-facepiece air-purifying respirator fitted with HEPA cartridges. The comment letter asserts, but does not show a basis for, the infeasibility of a PEL of 0.2 f/cc, compared with a PEL of 0.5 f/cc. Indeed, again, the fact that according to data provided by RCFC in the industry segment of "furnace related" with the majority of exposed employees in California (approximately 81%) they will probably all have to wear respirators regardless of whether the PEL is 0.2 or 0.5 f/cc does not support an argument for infeasibility of the one level over the other.

Contrary to the commenters' assertion, there is no existing federal OSHA standard in effect for RCF, and even if there were, at the level of 0.5 f/cc, the Board's establishing a lower PEL would not be relevant to the APA's stricture against regulatory duplication. With regard to consistency, the standard on this point is whether compliance with the PEL would make compliance with another regulation impossible, and the commenter has not shown, or suggested, that this would be the case. Nor has the commenters provided facts in support of their suggestion that the proposed PEL of 0.2 f/cc would "discourage or effectively prohibit use of RCF in California". With regard to necessity, the Board believes that evidence in animals, and in humans, indicates that exposure to RCF presents a risk of serious respiratory disease, that a PEL of 0.2 f/cc as proposed is necessary to maximize assurance that such disease does not develop, consistent with costs that nonetheless allow the material to continue to be used in California, and that costs will not be significantly higher in the dominant "furnace related" RCF industry in California than with the PEL of 0.5 f/cc recommended by the commenters.

Comment KB5: The 0.5 f/cc Recommended Exposure Guideline of the RFC Coalition is the effective federal standard for RCF, having been adopted as the NIOSH REL and endorsed by federal OSHA in lieu of promulgation of a federal PEL. The California Labor Code establishes a preference for state standards that are equivalent to the corresponding federal standards and require a detailed justification for departure from the federal requirements. Labor Code Section 142.3 provides in subsection (a)(2) that:

> The board shall adopt standards at least as effective as the federal standards for all issues for which federal standards have been promulgated under Section 6 of the Occupational Safety and Health Act of 1970 (P.L. 91-596) within six months of the promulgation date of the federal standards and which, when applicable to products which are distributed or used in interstate commerce, are required by compelling local conditions and do not unduly burden interstate commerce.

Furthermore, section 18(a) of the federal OSHA Act (29 USC section 667) governing state jurisdiction and plans provides:

> Assertion of State standards in absence of applicable Federal standards. Nothing in this Act shall prevent any State agency or court from asserting jurisdiction under State law over any occupational safety or health issue with respect to which no standard is in effect under section 6.

In cases where a state wishes to adopt a conflicting standard, section 18(c) provides a procedure for obtaining federal OSHA approval. Conditions for approval include a requirement that the conflicting state standards must be at least as effective as the federal standard, and "are required by compelling local conditions and do not unduly burden interstate commerce."

Although the RCFC REG of 0.5 f/cc has not been adopted by OSHA as a standard under section 6 of the OSH Act, it is certainly the "established" federal standard. It was expressly endorsed by OSHA in lieu of a Section 6 standard, and subsequently was adopted by NIOSH as a REL. In an appropriate case, it could be enforced by OSHA pursuant to the federal General Duty Clause. It is clearly the uniform national and industry standard and is recognized as such by both OSHA and NIOSH. Pursuant to both federal and California law, the proposed PEL of 0.2 f/cc for RCF should not be adopted in California until it has been justified as required by both the state and federal statutes and approved by federal OSHA.

Response: The Standards Board is only required, by the provisions of laws and regulations governing OSHA approved state plans, to adopt regulations that are "at least as effective as" their federal OSHA counterparts. There is no requirement, as the commenters suggest, for the Board to justify adopting a standard more stringent than a federal standard. Moreover, despite the suggestions of the commenters, with respect to a specifically enforceable regulation for RCF, none has been promulgated by federal OSHA. Finally, it is worth noting that the Board has received the standard preliminary approval from federal OSHA Region IX for the PEL proposed for RCF in a letter dated from Regional Administrator Ken Nishiyama Atha dated March 24, 2009. The letter states with respect to the PEL proposed for RCF:

> Refractory ceramic fiber (RCF) is proposed at 0.2 f/cc TWA based on the potential for RCF to cause or contribute to respiratory disease. Federal OSHA does not include a limit for RCF.

Dean Venturin, Refractory Ceramic Fibers Coalition, by letter dated March 13, 2009

Comment DV1: The RCF Coalition has engaged the University of Cincinnati to conduct a continuing study of RCF production workers that has been in progress for over 20 years, collecting data from respiratory questionnaires, lung function tests, chest X-rays, exposure monitoring, and worker mortality. The results of this study of workers exposed from 1953 to the present have shown no excess mortality related to all deaths, all cancer, or lung cancer, no statistically significant increases in interstitial findings (fibrosis), and no mesotheliomas. Through 1996, pleural plaques seen on chest X-rays in 2.7% of the workers were associated with RCF exposure. Pleural plaques are considered a marker of exposure and not disease.

Response: The Board applauds the work that the RCF manufacturers have sponsored by the University of Cincinnati researchers which have yielded published scientific studies on radiographic changes, pulmonary function changes, and mortality among some RCF-exposed workers. However for the reasons detailed below, the Board approaches with caution drawing from these data the conclusion that 0.5 f/cc based primarily on current feasibility of achievement is the appropriate value for the PEL for RCF.

The NIOSH Criteria Document provided this summary of those studies (page 99 of the NIOSH document):

> NIOSH considers the discovery of pleural plaques in U.S. studies of RCF manufacturing workers to be a significant finding because the plaques were correlated with RCF exposure [Lemasters et al. 1994; Lockey et al. 1996]. In addition, NIOSH considers the respiratory symptoms and conditions (including dyspnea, wheezing, coughing, and pleurisy) observed in RCF workers to be adverse health effects associated with exposure to airborne RCFs [Lemasters et al. 1998; Lockey et al. 1993; Trethowan et al. 1995; Burge et al. 1995; Cowie et al. 1999].
>
> An association between inhaling RCFs and fibrotic or carcinogenic effects has been documented in animals, but no evidence of such effects has been found in workers in the RCF manufacturing industry. The lack of such an association could be influenced by the small population of workers in this industry, the long latency period between initial exposure and development of measurable effects, the limited number of persons with extended exposure to elevated concentrations of airborne fibers, and declining occupational exposure concentrations.

The ACGIH documentation for its TLVs for synthetic vitreous fibers (SVFs), notes that among this group of materials only RCFs have been found to produce cancer in animals by inhalation, other SVFs producing cancer only by unusual routes of exposure such as intrapleural and intraperitoneal injection and possibly intratracheal injection. ACGIH in the documentation for its TLV of 0.2 f/cc for RCF, in language similar to the statement of NIOSH above, states:

> The TLV–TWA for RCF is set at an intermediate level between asbestos (0.1 f/cc) and other types of SVF (1.0 f/cc). The recommended TLV –TWA of 0.2 f/cc for RCF reflects concerns based on pleural and lung function abnormalities already seen among exposed cohorts, indicating that the health risks of RCF are closer to asbestos than other types of SVF. Similarly, an A2, Suspected Human Carcinogen, notation is assigned for RCF, based on the following: 1) RCF cause lung fibrosis, lung cancer, and mesothelioma in animals exposed via inhalation; 2) these health effects resemble those of asbestos (a confirmed human carcinogen); and 3) RCF exposures in humans have been too brief to date to allow an accurate assessment of the risks of lung cancer and mesothelioma.

With regard to the University of Cincinnati findings on pulmonary function which the Cal/OSHA PEL committee found to be significant, the NIOSH 2006 Criteria Document states the following (on page 78):

> The analysis found decreases in FVC and FEV1 for workers employed >7 years in production compared with nonproduction workers. In longitudinal analyses of followup production years (i.e., from initial PFT to final PFT) and followup cumulative exposure (i.e., from initial PFT to final PFT), neither of these variables had an effect on FVC or FEV1. These results led the authors to conclude that more recent exposure concentrations during 1980–1994 had no adverse effect on the longitudinal trend of pulmonary function [Lockey et al. 1998]. Decrements in FVC and FEV1 noted in initial cross-sectional analyses of PFT data were believed to be related to earlier higher exposure concentrations.

By the above, NIOSH in its 2006 Criteria Document notes the findings of decreased pulmonary function by the University of Cincinnati researchers among RCF exposed workers. NIOSH notes that the later findings of no decrements in subsequent pulmonary function testing were believed by the researchers (in Lockey et al. (1998) to have been accounted for by the lower levels of exposure to RCF in subsequent years. The Board believes this may be one possible or partial explanation.

However, Lockey et al. (1998) note the possibility of a "healthy worker effect" as a possible alternative or partial alternative explanation for the findings of no pulmonary function decrement in the later years of the study:

> Selection bias can occur in longitudinal studies with repeated measures since loss to follow-up or nonparticipation can be associated with decreased pulmonary function values. In the current study there was a significant difference with respect to percent of FVC and FEV_1 values below 80% of predicted values between production workers who left RCF employment and the production participant.

Specifically, Lockey et al. (1998) noted that among the entire cohort of 569 RCF workers in this study, 191 who were otherwise eligible for pulmonary function testing only completed 4 of the 7 test sessions along with 2 others who did not participate in any test sessions:

> Of the 193 workers in the nonanalysis group, 107 left employment because of retirement, layoff, another job, disability or death, and 86 did not participate because of medical exclusion criteria (elevated blood pressure, n = 20, acute illness, n = 5), vacation, or refusal. Two men provided no measurements. On average the nonanalysis group was older, smoked more, weighed more, and had lower height-adjusted and percent predicted lung function values at initial test. Mean numbers of years of RCF production employment were 7.0 and 7.3 in the analysis and nonanalysis groups, respectively.

The limitations of the Cincinnati studies are particularly significant because the population of workers in the RCF manufacturing industry is relatively small (the epidemiology studies noted above by NIOSH generally consisted of cohorts with fewer than 1,000 workers) and young, and often with periods of exposure to RCF being relatively short in terms of presenting risk of disease. In the mortality study of Lemasters et al.(2003) cited in Dean Venturin's written comments, the mean age of study participants was 51 years (median 50, range 23-87), duration of RCF production employment 9 years (median 5, range 0.1 to 42), and individuals were identified as having a production job if they spent at least 10% of their time in the production areas of the facility. Highlighting these limitations of the study, the authors note:

> There was only a 40% power to detect a 2-fold increase in lung cancer, but 90% power to detect a 3-fold increase.

Even with the inherent limitations of the epidemiology studies conducted in the industry, the Board can conclude that RCF does appear to be significantly less hazardous than asbestos. Dean Venturin's written comment on the Cincinnati data states:

> Thus, this long term epidemiology study has demonstrated both an absence of interstitial fibrosis, no increased mortality risk, and no decrement in lung function associated with current exposures.

The Board does not dispute the accuracy of this statement as far as it goes. However, the Board believes that a thorough reading of these studies shows that, in light of the findings, as discussed above, and the inherent limitations of their populations and methods, care must be taken before concluding that RCF has been substantially proven through human studies to have very limited or no significant potential for causing fibrosis, increased mortality, or lung function decrement at the current levels of exposure of the Cincinnati cohort of RCF manufacturing workers.

Comment DV2: RCFC commissioned a risk assessment based on bioassay data from animal studies also commissioned by RCFC and conducted in the late 1980s. The resulting calculated risk for a 70 year old worker with 30 years of exposure to 1 f/cc was 3.7×10^{-5} (maximum likelihood estimate) for a nonsmoker and 1.5×10^{-4} for a smoker. Using the findings of this study by Moolgavkar, Turim and Brown (2003), summarized the 95% upper bound risk of excess lifetime lung cancer for nonsmoking workers as:

- 3×10^{-5} for a 1 f/cc exposure
- 1.5×10^{-5} for a 0.5 f/cc exposure
- 0.3×10^{-5} for a 0.1 f/cc exposure
- Separately, Fayerweather (1997) extrapolated rat data to human data using a linearized multistage model and found at exposures of 1 f/cc, the excess lifetime risk of developing lung tumors was 3.8×10^{-5} (maximum likelihood estimate).

Subsequently, others have modeled animal data yielding similar risk estimates. These consistent results indicate that the lifetime excess cancer risk from worker exposure to RCF is within the range generally considered by OSHA and EPA as acceptable.

Response: See the response to the oral comment of Julia Quint regarding RCF, in which Board Member Frisch asked about the quantitative risk assessment finding in animal studies on RCF.

Comment DV3: A PEL of 0.2 f/cc for RCF would be at least three times as stringent as the current Cal/OSHA PEL for asbestos (a known human carcinogen) of 0.1 f/cc given that only about 14% of the airborne asbestos fibers are visible using Phase Contrast Microscopy analysis. Therefore, at the asbestos PEL of 0.1 f/cc as measured by PCOM, the real airborne asbestos concentration is (0.1) / (0.14) = 0.71 f/cc. RCF fibers have generally larger diameters, and approximately 94% of RCF fibers are visible using Phase Contrast Microscopy. The real airborne RCF concentration (measured by PCOM) at the proposed PEL of 0.2 f/cc is (0.2) / (0.94) = 0.21 f/cc. So, the proposed PEL for RCF is more stringent than the PEL for asbestos by the ratio of these real concentrations, or a factor of (0.71)/(0.21) = 3.38.

Response: The Board does not dispute the comment with respect to differences in fiber diameter distribution between asbestos and RCF. However, the Board does not find the comment to be compelling with respect to modifying the PEL, originally proposed. In comparing the Federal and Cal/OSHA PEL for asbestos, and that proposed for RCF, it is important to recognize that Federal OSHA stated in the final notice for its asbestos rule in the Federal Register of August 10, 1994 that the cancer risk level associated with asbestos exposure of 0.1 f/cc was 3.4 per 1,000 workers. As a result of feasibility concerns, the OSHA PEL for asbestos is set well above the 1/1,000 maximum risk target level suggested in the decision of the U.S. Supreme Court on OSHA's benzene standard in 1980 [Industrial Union Dept. v. American Petroleum Institute, 448 U.S. 607 (1980)]. In fact, the multiple of 3.4 is almost exactly the same as the multiple by which the comment suggests a PEL of 0.2 f/cc for RCF is excessively high due to the fiber counting issue he notes. To address the excess risk remaining at the asbestos PEL, OSHA adopted extensive mandated work practices for certain tasks that, as stated in the Federal Register Notice of August 10, 1994:

> …will, in most situations, result in employee exposures well below the PEL (of 0.1 f/cc for asbestos)

No mandated work practices are proposed for RCF in this rulemaking. In fact, unlike the asbestos standard which, like other similar OSHA comprehensive standards for carcinogens, includes extensive programs for

air monitoring, medical surveillance, and hygiene facilities and practices, the proposal for RCF is only for a PEL, no program requirements are being proposed. Additionally, the asbestos PEL includes a Ceiling limit of 1 f/cc, adding to the stringency of that standard. For all of the reasons stated, the Board does not believe that this comment presents a compelling case that the proposed PEL of 0.2 f/cc for RCF is excessive when compared to the PEL for asbestos.

Comment DV4: Both the Hazard Evaluation System and Information Service (HESIS) within the California Department of Public Health, and the Office of Environmental Health Hazard Assessment (OEHHA) within Cal/EPA have recognized that the NIOSH Recommended Exposure Level (REL) of 0.5 f/cc for RCF is based on quantitative risk assessment, whereas the ACGIH TLV was not. HESIS recommended a PEL based on the NIOSH REL for this reason, and because the risk-based value is more consistent with Cal/OSHA precedents and the applicable legal requirements.

Response: See the response to Comment KB1 of Kurt Blase, representing the Refractory Ceramic Fibers Coalition.

Comment DV5: RCFC respectfully, but emphatically, challenges the adjustments made by the Board to information which it provided on the potential costs of the proposed PEL of 0.2 f/cc, and believes that the Board misinterpreted the cost data submitted by RCFC in its detailed comments provided below. The compliance cost estimate provided by the Coalition to the Board previously was developed using the same cost elements and conventions employed by OSHA in its regulatory impact analysis of various PELs. The application by the Board of a 70% adjustment figure to the cost estimate developed by the Coalition is entirely inappropriate even if certain cost elements are eliminated from consideration.

Table 2 (in the comment letter) shows the detailed data originally submitted by the Coalition (Allshouse, 2007) by Everest Consulting Associates for the various industry segments that were summarized in an informal RCFC submittal to the Division prior to rulemaking (RCFC, 2007). The costs included in Table 2 differ slightly from those originally submitted (Allshouse, 2007; RCFC 2007) as these have been adjusted upward for inflation (using the Marshall & Swift index) to 3rd quarter 2008 values, rather than the 2007 costs originally submitted.

The new total annual cost (excluding the "other" segment of California RCF users) adjusted for inflation is approximately $5.2 million, rather than $4.6 million as submitted originally. Omitting costs for change rooms, lockers, shower rooms, lunch rooms, regulated areas and medical surveillance as was done by the Board, reduces the current cost estimate to $4.2 million. The Board adjusted the total estimated cost suggested by RCFC to 35% of the value based on omission of these cost elements. This was done based on the assumption, per data provided by RCFC, that 65% of RCF workplace measurements are at or below 0.2 f/cc.

The Coalition believes there are three errors in this calculation, the first error of which is: Some of the costs are for engineering controls or other "indivisible" elements. Controls are either installed or they are not—they are not on a per-worker basis. The other two errors suggested by the commenter are summarized and responded to below as
Comments DV6 and DV7.

Response: Table 3 in the comment letter contains updated cost estimates based in part upon deletion of costs for change rooms, lockers, shower rooms, lunch rooms, regulated areas and medical surveillance in

recognition of the fact that these elements, although potentially important for hazard control, are not required by the PEL being proposed.

These changes yield the RCFC's estimated annual costs per employee adjusted for inflation to third quarter 2008 in each of the three industrial sectors for which RCFC provided information (including estimates of the number of employees):

Vacuum formers (70 California employees):	$11,381
Fabrication (80 California employees):	$ 7,018
Furnace related (639 California employees):	$ 4,503

Multiplying the RCFC estimated annual per employee costs times the number of employees in each industrial category and then adding the costs in the three categories, the RCFC total annual estimate for the cost of compliance with the proposed PEL is, roughly, $4.2 million dollars per year (roughly $800,000 for vacuum formers, $560,000 for fabrication employers, and $2.9 million for furnace related employers).

In summary, the Board's evaluation of the RCFC cost estimates for a PEL of 0.2 f/cc leads it to conclude that the values are not supported by the information in Dean Venturin's letter, or in a 1999 report discussed below, and in fact overstate potential costs of the proposed PEL by a factor of approximately four. Essential conclusions, as detailed in the discussion below, are:

1. The Board accepts the cost estimates in Dean Venturin's letter for HEPA vacuums and vacuuming in the furnace related segment of the industry ($502), engineering controls in the vacuum formers segment of the California industry ($1,363), the respirator cost estimate in the furnace related segment of the industry ($394), and the cost estimate in all three industry segments for Training, Compliance Program, Fit Testing, and Records ($149 to $339).

2. The Board as explained in detail below believes the following cost estimates in Dean Venturin's letter overstate the potential annual per worker costs of the proposed PEL:

    a. For HEPA vacuuming equipment and labor in the vacuum formers segment of the California industry the Board has adjusted the annual per employee cost estimate from $2,992 to $500 as explained in detail below.

    b. For air sample labor and analysis the Board, as explained in detail below, has adjusted the per employee annual cost estimate in all three named industry segments from $2,298 to $500.

    c. For disposable personal protective equipment (PPE), because it is not required by the proposed PEL, the Board has adjusted the per employee annual cost estimates of $2,298 in the vacuum former and fabrication segments to zero, and in the furnace related segment from $299 to $0.

    d. For respirator costs in the vacuum formers and fabrication industry segments, the Board has adjusted the per employee annual cost estimates from $1,602 to $600.

Although Dean Venturin's 30-page comment letter reflects significant differences in cost estimates for the three industry segments he discusses, the letter provides no explanation for these differences, nor any justification for the scale of the costs suggested. However, it was possible to obtain this more detailed information for the RCFC cost estimates from a report in a letter referenced in Dean Venturin's written comment. That letter (Document Relied Upon No. 27 in the Initial Statement of Reasons) is correspondence to the Division from John Allshouse of Everest Consulting dated December 7, 2007. The letter of John Allshouse indicates that its cost estimates, which were discussed in the Initial Statement of Reasons for this rulemaking, were based upon a report dated February 1999, prepared for the Refractory Ceramic Fiber Coalition by Everest Consulting of Cranbury, New Jersey and titled *Evaluation of a Potential 0.5 f/cc or 0.1 f/cc Permissible Exposure Limit (PEL) for Refractory Ceramic Fiber (RCF).* This report was also referenced as being the basis of the cost estimates in the letter from RCFC by Daniel Maxim of Everest Consulting dated September 27, 2007; (Document Relied Upon No. 26 in the Initial Statement of Reasons).

For the three named industry segments identified by RCFC as operating in California, Dean Venturin's letter provides the following annual per employee detailed cost estimates for the proposed PEL of 0.2 f/cc:

	VACUUM FORMERS	FABRICATION	FURNACE RELATED
HEPA vacuums	$2,992	0	$502
Engineering controls	$1,363	0	0
Monitoring program	$2,970	$2,970	$2,970
Disposable PPE	$2,298	$2,298	$ 299
Respirator costs	$1,602	$1,602	$ 394
Training, Compliance Program Fit testing, & Records	$ 156	$ 149	$ 339
RCFC annual costs per worker	$11,381	$7,019	$4,504

Based on information contained in the February 1999 Everest Consulting Associates report, the Board believes that several of these annual cost estimate values should be adjusted, as follows:

HEPA Vacuums

In Vacuum Formers: As detailed on pages C-16 and C-17 of the 1999 Everest Consulting Report, the value stated for HEPA vacuums is based upon compliance with the requirement of OSHA's asbestos standard that all surfaces must be maintained as free as practicable of dust accumulations, California's standard for general industry (Title 8 Section 5208) having the same requirement. However, this is not a specific requirement of the proposed PEL for RCF, although it can contribute to controlling exposures in many situations, and it could be argued that it is a practice that employers with workers exposed to RCF should already be including in their exposure control measures. More significantly, however, as detailed on page C-17 of the 1999 Everest Consulting Associates Report, only about 7% of the estimated cost in this category per employee was for the vacuum, power, and consumables such as filters and vacuum bags. 93% of this estimated category of cost in the 1999 Everest Consulting Report is apparently for labor, i.e. the cost of time spent vacuuming floors and other surfaces to comply with the asbestos standard for housekeeping, with attribution of approximately 2 hours per day of each employee's time for such cleaning. The Board does not believe this is a reasonable estimate for the actual cost of complying with the proposed PEL of 0.2

f/cc. The 1999 Everest Consulting Report quotes a cost estimate (in 1999) for a 2 horsepower HEPA vacuum of $885, and $5,265 for a more powerful 5 horsepower unit, an operating life of 5 years, and 1 HEPA vacuum per 5 employees. Assuming a middle-range estimate for the purchase price of $2,500, this would translate into a per employee cost for the vacuum of about $500. With the 5-year operating life assumption of the 1999 Everest Consulting Report, this would translate into a per year per employee cost of $100 for the HEPA vacuum itself. A similar amount per employee per year appears reasonable for consumables and power based upon the figures in the 1999 Everest Consulting Report. The Board would not normally include in its cost estimate for a PEL the cost of labor for an activity incidental, rather than central, to achieving compliance with the PEL. Nonetheless, in this instance, so as to assure fairness to the commenter, and in recognition of their work done on the cost estimate, the Board believes it is not unreasonable to attribute a labor cost of $300/employee/year for housekeeping expenditure in vacuum formers, bringing the total to the category of "HEPA Vacuums" in that industry to $500/employee/year.

In Fabrication: The RCFC does not include a cost for HEPA vacuums in its cost estimate for Fabrication employers.

In Furnace Related: The Board believes the estimate of $502/employee/year for HEPA vacuums in construction is reasonable, based primarily on the cost of the vacuum and consumables. The Board suspects that the life of a HEPA vacuum is likely to be shortened by movement between and use at different worksites. Furthermore there may be more use of vacuum consumables in cleaning up such worksites. However, as such clean-up is clearly incidental to the work being conducted, the Board notes that the OSHA and Cal/OSHA standards for asbestos in construction do not include the same requirement maintenance of clean surfaces as is found in the standard for general industry.

Engineering Controls

In Vacuum Formers: Vacuum formers are the only industry segment for which RCFC suggests costs in this category. The 1999 Everest Consulting Associates report does not contain a detailed discussion of these costs as it does for HEPA vacuums and housekeeping as discussed above, and for air monitoring as discussed below. However, the RCFC value of $1,363 is accepted as the Board presumes that at least some of these employers will need to install engineering controls to achieve compliance with the PEL of 0.2 f/cc, and even those that do not will incur costs for maintenance, repair and eventual replacement.

In Fabrication: The letter does not cite any costs for engineering controls in this industry segment.

In Furnace Related: The letter does not cite any costs for engineering controls in this industry segment.

Monitoring Program

In Vacuum Formers, Fabrication, and Furnace Related: In the estimates for all three industry segments the RCFC cites a figure of $2,970 for annual costs, per employee, for an air monitoring program to comply with the proposed PEL of 0.2 f/cc. It appears from pages C-7 and C-8 of the 1999 Everest Consulting Associates report that this number is derived from the following: An assumption of four full-shift exposure assessments per year per employee by an outside consultant

adjusted from a 1999 cost estimate of $534 per full-shift assessment. The 1999 estimate of $534 per full-shift employee assessment is based upon a per sample analysis cost of roughly $50, as well as the travel and labor costs of an industrial hygiene technician.

The Board believes that the RCFC's estimates of costs for monitoring programs are excessive. Even under a comprehensive chemical standard for which the 1999 Everest Consulting Associates report was produced, there would not be a requirement for monitoring of the exposure of every employee, unless they were all doing distinct tasks with distinct levels of potential for exposure. Rather what is required in OSHA and Cal/OSHA comprehensive chemical standards is 8-hour sampling that is "representative" of what employees are exposed to, based upon monitoring of employees conducting similar work. Furthermore, for PELs in section 5155, the requirement for monitoring in subsection (e)(1) is:

> Whenever it is reasonable to suspect that employees may be exposed to concentrations of airborne contaminants in excess of levels permitted in section 5155(c), the employer shall monitor (or cause to have monitored) the work environment so that exposures to employees can be measured or calculated.

While this monitoring requirement in section 5155 may contribute to employers developing representative exposure estimates for all operations and employees in their business, the central purpose of the requirement is to help assure that control measures are applied where needed to maintain exposures below the PEL, and that controls are effective in maintaining exposures below the PEL. For this purpose full-shift sampling is not required – sampling can be task based and the employer's knowledge of the maximum time an employee may conduct the sampled operation during a workshift, or the exposures from combinations of operations over the course of a workday, can be used by the employer to determine when and where application of exposure control measures is needed. Therefore, full-shift sampling envisioned by the RCFC cost estimate will not necessarily be needed, and may not even be the most effective approach to assessing exposure, as the results obtained may be less a function of the exposure potentially caused by a particular operation and more the result of the time spent by the worker on the operation on the particular day that the air sampling is conducted.

Furthermore, especially in the furnace related businesses which constitute 81% of the California workforce in the RCFC estimates for these three named industry segments, there is the potential for conduct of a significant amount of the air sampling by the employer themselves, especially with the assistance of the RCFC Product Stewardship Program helping them obtain the proper equipment and facilitating their working with an outside industrial hygiene consultant to provide the technical oversight of monitoring required by section 5155. This approach would save much of the travel and labor cost of the industrial hygiene technician included in the RCFC estimate for the monitoring program, and could probably also be used to some extent by the vacuum formers and fabrication industry segments.

In light of the above, the Board believes a more reasonable estimate for the cost of exposure monitoring attributable to a PEL of 0.2 f/cc would be in the range of $500 per employee per year. Furthermore, given that RCFC's own assessments of exposures in furnace related work (Maxim et al., 2008) is that it can be expected to frequently be above 0.5 f/cc, even if the higher PEL of 0.5 f/cc recommended by RCFC were to be adopted by the Board, it appears that employers in the "furnace

related" industry segment would generally be requiring their employees to wear at least half-facepiece air-purifying cartridge respirators during furnace work of all but the briefest duration. Knowing that employees will generally need to be using at least this level of respiratory protection during active work with RCF and, hopefully, that the exposures will generally not exceed 10 times the PEL and so this level of respiratory protection should be effective, extensive air monitoring should not be required for employees in the furnace related industry segment in order to comply with a PEL of either 0.5 or 0.2 f/cc.

Disposable Personal Protective Equipment (PPE)

In Vacuum Formers, Fabrication and Furnace Related: For vacuum formers and fabrication, RCFC estimates an annual per employee cost of $2,298 for disposable PPE, and $299 apparently based on non-continuous work with RCF among employees in the furnace related sector. Personal protective equipment such as protective clothing, gloves, head protection etc. are important elements of overall exposure control and prevention of exposures of family members and others that employees working with hazardous substances may encounter outside of the workplace. However, such PPE is not a requirement of section 5155 and would not be directly related to maintaining compliance with the proposed PEL, or a PEL of 0.5 f/cc as is recommended by RCFC. Therefore, the Board adjusts the cost estimate for disposable PPE to zero.

Respirator Costs

In Vacuum Formers, Fabrication, and Furnace Related: For vacuum formers and fabrication, RCFC estimates an annual per employee cost of $1,602 for respirators, and $394 apparently based on non-continuous work with RCF among employees in the furnace related sector. For the air-purifying cartridge respirators that the RCFC's extensive monitoring data suggests would be a satisfactory level of protection needed to comply with the proposed PEL of 0.2 f/cc in all, or nearly all work situations, the annual cost figure of $1,602 appears to be excessive. On pages C-11 and C-12 of the 1999 Everest Consulting Associates report, this cost estimate is broken down roughly as follows: 2% for the cost of the respirator, 45% for the cost of weekly HEPA filter replacement, 9% for respirator cleaning supplies, and 43% for the labor cost for daily cleaning of the respirator facepiece (6 minutes per day x 250 days/year at $19.99 per hour). The Board believes these cost figures are excessive. Respirators are unlikely to be needed daily by all workers, and weekly replacement of the HEPA cartridges is not a requirement. Daily cleaning of respirator facepieces while a good practice is also not required, unless the facepieces are being exchanged among employees on a daily basis. Therefore, the Board believes a reduction of the RCFC cost estimate for respirators in vacuum formers and fabrication to $600 per employee per year ($50 per employee per month) is reasonable. For the "furnace related" industry segment, it appears from RCFC's monitoring data for that respirators are likely to be needed during all or most such operations regardless of whether the PEL is set at 0.2 f/cc or at 0.5 f/cc, and the needs for cleaning and facepiece replacement may be greater in this industry segment due to operations being at non-fixed worksites. Therefore, the Board believes the RCFC respirator cost estimate for this industry segments is reasonable.

Training, Compliance Program, Fit Testing, Recordkeeping

In Vacuum Formers, Fabrication, and Furnace Related: The cost estimates of RCFC for these items are not significant to the overall cost estimate and do not appear unreasonable to the Board.

BOARD MODIFIED COST ESTIMATES BY SEGMENT BASED ON DISCUSSION ABOVE:

	VACUUM FORMERS	FABRICATION	FURNACE RELATED
HEPA vacuums	$ 500	0	$ 502
Engineering controls	$1,363	0	0
Monitoring program	$ 500	$ 500	$ 500
Disposable PPE	$ 0	$ 0	$ 0
Respirator costs	$ 600	$ 600	$ 394
Training, Compliance Program Fit testing, & Records	$ 156	$ 149	$ 339
RCFC annual costs per worker by industry segment, revised for Board assumptions	$2,963	$1,249	$1,735

Based on the numbers of employees in each industry segment in California noted in Dean Venturin's letter, and the Board's adjustment of the cost estimates suggested in the letter, the following would be the total annual costs of the proposed PEL of 0.2 f/cc for the three named industry segments in California:

Vacuum formers:	(70 California workers)	$28,330
Fabrication:	(80 California workers)	$99,920
Furnace related:	(639 California workers)	$1,108,665

This yields a total preliminary annual cost estimate for the proposal of approximately $1.43 million, compared with Dean Venturin's estimate of $4.2 at the top of page 19 of his comment letter.

Taking into account the "other" RCF industry segment in California which Dean Venturin estimates constitutes about 40% of the overall California employee count, as explained in the response to Comment DV7 below, Figure 4 in the commenter's letter reflects that in the three named RCF industry segments in California for which the commenter provided cost estimates, approximately 50 percent of 631 exposure measurements in California, and 4,831 nationwide, recorded by Dean Venturin's organization were less than 0.2 f/cc. While this number may not be exactly parallel to the fraction of employers or employees whose exposures are already in compliance with the proposed PEL of 0.2 f/cc, it is suggestive of that.

Taking the estimate suggested by the commenter's Figure 4 of 50 percent of exposures already being less than the 0.2 f/cc level proposed, the Board believes that one approach to further adjusting its total cost estimate is to divide the $1.43 million total cost figure derived above by a factor of 2, for a total cost estimate of $715,000 per year for the proposed PEL of 0.2 f/cc.

Taking this a step further, in response to Comment DV6 of Dean Venturin summarized and responded to below with regard to the need for employers to control exposures to the level of 0.1 f/cc in order to be confident of compliance with the proposed PEL of 0.2 f/cc, multiplying by 1.4 (to take into account the "other" industry category as noted immediately above) the roughly 50 percent of exposure measurements found to be below 0.1 f/cc according to Figure 4 in Dean Venturin's comment letter, yields an adjustment factor of 70% that can be applied to the Board's $1.43 annual cost estimate, yielding a value of just over $1 million total annual cost for the PEL of 0.2 f/cc. , This value is slightly less than than 25% of the cost estimate of $4.2 million suggested in Dean Venturin's letter.

However, it is important to note further that among the three named industrial segments detailed in Dean Venturin's letter, the commenter estimates that the majority of employees working with RCF in California (81%) are in the "furnace related" industry segment. An attachment to the commenter's letter (Maxim et al. 2008) suggests that exposures in this segment can be above 1 f/cc and are frequently above 0.5 f/cc. Figure 12 in the Maxim et al. paper includes a bar graph appearing to show measured RCF concentrations in the "removal" phase of work being in the range of 1.2 f/cc. Also, in the Maxim et al. paper, Figure 17 suggests that for the functional job category of "removal" roughly 40% of sample results in the industry sponsored air sampling program were above 0.5 f/cc, while for "installation" 20% of the measured values were above 0.5 f/cc. Furthermore, with regard to the use and availability of engineering controls in the furnace related segment of the industry, the following should be noted:

1. This statement on page D-61 of 172 in the attachment to the commenter's letter:

   > Because many major removal jobs occur in confined spaces (inside furnaces), and because major removals are infrequent at any given site, engineering controls are generally not applicable.

2. Confirming the above statement above, Dean Venturin's letter does not include any estimate for engineering controls in their cost estimate for the "furnace related" segment of the industry in California.

If, in fact, exposures to RCF in the "furnace related" industry segment can frequently be above 0.5 f/cc as indicated by the data in the Maxim et al. 2008 paper, and reliable engineering controls are not available for the furnace related segment of the industry as Dean Venturin's own documents state, then given the information that has been presented by RCFC in this rulemaking, and the standard protection factor of 10 for a half-facepiece cartridge respirator, and 50 for a full facepiece respirator, there should be no real difference in costs in the furnace related segment for the proposed PEL of 0.2 f/cc, or the commenter's preferred value of 0.5 f/cc.

Based on the analysis above, the Board believes that Dean Venturin's cost estimate for the proposed PEL of 0.2 f/cc by itself overstates by a factor of between 3 and 4 fold the costs that California employers in the three named industry segments might incur. Furthermore, if the 0.5 f/cc PEL recommended by the commenter is taken into account, as explained immediately above given that in the furnace related industry segment which dominates RCF use in California exposures are frequently above 0.5 f/cc, there appears to be little significant difference in the cost to the dominant industry segment in California of "furnace related" work with the proposed PEL of 0.2 f/cc as opposed to the 0.5 f/cc recommended by the commenter.

Comment DV6: The second error in the Board's estimate of costs based on air sampling results provided by RCFC is the assumption that 65% of California RCF workers are already being protected to the level of the proposed PEL of 0.2 f/cc. This approach taken by the Board in its cost estimates of compliance with a PEL of 0.2 f/cc rests on the erroneous assumption that worker exposures would only have to be reduced to 0.2 f/cc to comply with the proposed PEL. Given variability of exposure levels in the workplace, as a practical matter, to ensure compliance with a PEL of 0.2 f/cc for RCF, it will be necessary for employers to reduce exposures to approximately 0.1 f/cc.

Response: As detailed in the response to Comment DV5 of Dean Venturin in developing the Board's estimate of the total cost of the proposed PEL based upon information provided in his comment letter, with regard to the need for employers to control exposures to the level of 0.1 f/cc in order to be confident of compliance with the proposed PEL of 0.2 f/cc as suggested in the comment, an adjusted annual total cost of $1.12 million, about 25% of the commenter's estimate, is calculated by taking into account the indication of Figure 4 in the commenter's letter that about 50 percent of exposure measurements between 1993 and 2006 were found to be below 0.1 f/cc. Adjusting for the "Other" industry segment as discussed in the response to comments DV5 and DV7 yields an adjustment factor of 70% that can be applied to the Board's $1.6 million unadjusted cost estimate, and a final value of $1.12 million total cost, slightly more than 25% of the cost estimate of $4.2 million suggested in Dean Venturin's letter.

However, as also noted in the response to Dean Venturin's Comment DV5, because slightly more than 80% of California employees affected according to the comment letter's data are in the "furnace related" segment of the industry and can often be expected to work in operations where engineering control measures are not generally available, most operations in this industry segment with exposures above 0.5 f/cc will require respiratory protection regardless of whether the PEL is 0.2 f/cc as proposed by the Board, or the 0.5 f/cc preferred by the commenter. Therefore, by this data, for the 81% of California RCF workers in workplaces with significant exposures to RCF, the exposure control measures, and associated costs, will be the same with a PEL of 0.2 or 0.5 f/cc.

Comment DV7: The third error in the Board's cost estimate is a misinterpretation of the data presented in Figure 4 of the comment letter. This figure is entitled *Weighted percentage of TWA measurements above any candidate PEL based upon data collected from 1993 – 2006.* The data in Figure 4 applies to the entire California cohort of 1,262 workers including 474 workers RCFC categorized as "Other" for whom costs of the proposed PEL were assumed to be zero. If an adjustment is to be made to the Coalition's cost estimate based on the data in Figure 4 previously provided to the Board, it should be based on the distribution of the fraction of the cohort for which costs are assumed, and should not include the estimated 474 workers for whom no incremental costs were assumed in RCFC's cost of compliance estimates.

Response: Dean Venturin's comment letter did not detail what an appropriate adjustment for the 474 California workers in the "Other" segment might reasonably be. Thus, in taking into account the error suggested by the commenter in looking at Figure 4 of his letter, it appears appropriate to assume, as the comment suggests, that the findings of low exposures in the "Other" industry segment, compared to those found in the three named segments, is significantly affecting the percentage of exposures that figure 4 suggests are currently below the proposed PEL of 0.2 f/cc. RCFC reported 474 workers in the "Other" category in California, from among the total number of 1,263 in all segments, or 38%.

In the absence of additional information, it seems reasonable to assume that all of the exposures measured for this group are 0.2 f/cc or less, and measurements in this segment constitute about 40 percent of the

measurements taken. Then, taking Dean Venturin's suggestion and adjusting the outcome of Figure 4, multiplying by 1.4 the value used previously by the Board of only 35% of exposures being over 0.2 f/cc as suggested by Figure 4 in the comment letter, translates into viewing Figure 4 as having, from just among the named industry segments (vacuum, fabrication, furnace) approximately 50% of exposure measurements being over the proposed PEL of 0.2 f/cc. As detailed in the response to comment DV6 of Dean Venturin above, if instead a threshold of 0.1 f/cc is viewed as being needed to be confident of compliance with a PEL of 0.2 f/cc, then the value of 1.4 to account for the "Other" industry segment can be used to adjust the Board's total cost estimate for the PEL to $1.12 million per year, approximately 25% of the estimate in the commenter's letter.

Dave Danner, Bricklayers and Allied Craftworkers Local 3, AFL-CIO, by electronic mail dated March 16, 2009

Comment: Among the PELs in the proposal, ceramic fiber would be the only material listed that Dave Danner's company works with. Currently there is no PEL established for ceramic fiber. The refineries and their refractory contractors have been treating ceramic fiber in a manner consistent with asbestos fibers for at least 10 years. They have been trying to prevent another round of legal actions like they had with asbestos. Therefore, their contractors indicate no opposition to this standard.

Response: The Board thanks Dave Danner for this information on his union members' experience with their employers' response to RCF work in the petrochemical industry.

Julia Quint, by letter dated March 18, 2009

Comment: Julia Quint supports the proposed PEL of 0.2 f/cc 8-h TWA for refractory ceramic fiber. The commenter notes that based on a quantitative risk analysis conducted by NIOSH, the risk of cancer at a level of 0.5 f/cc is 0.73 to 1.2 excess cancers per 1,000 workers, while at 0.2 f/cc the excess cancer risk will be less than 1/1,000 over a working lifetime. The commenter states that this cancer risk at 0.2 f/cc is still significant, but is consistent with the goals set by federal OSHA and Cal/OSHA when quantitative risk analysis was used to derive health-based PELs for other regulated carcinogens such as hexavalent chromium.

Response: The Board thanks Julia Quint for her participation in this rulemaking process.

Michael Smith, WorkSafe, and 12 Co-Signers, by letter dated March 19, 2009

Comment: The commenters support the proposed PEL of 0.2 fibers/cc as an 8-hour TWA. The commenters cite the NIOSH Criteria Document as providing a strong basis for the recommended PEL and suggest that ACGIH and NIOSH wisely recommend a precautionary approach to minimizing the risk of respiratory disease from employee exposure to RCF. The commenters also support the conclusion in the Initial Statement of Reasons that the proposed PEL will not have a significant cost impact and suggest that the PEL proposed strikes an appropriate balance between what is achievable for industry and what is necessary to protect human lives consistent with Supreme Court precedent.

Response: The Board thanks the commenters for their participation in this rulemaking process.

Paul Darnell, Industrial Insulations, by letter dated March 19, 2009

Comment: Paul Darnell's company uses about 400,000 pounds per year of RCF, and when they work with this material, they follow the recommendations of the RCF industry's Product Stewardship Program which includes a recommended exposure guideline of 0.5 f/cc. With the current energy crisis and concerns about global warming, they believe it is important to promote use of energy efficient products. His company is not aware of any reasonably available substitute for RCF for the purposes for which they use it. Paul Darnell and his company are dedicated to the protection of their work force, but it is their understanding that the industry's epidemiological studies of RCF production workers have found no excesses of disease in those RCF workers most heavily exposed. They are not aware of any health problems in their work force attributable to RCF exposure.

His company would not be able to comply with the proposed PEL of 0.2 f/cc in all operations with their current engineering controls. They are not aware of any available controls that they are confident would allow them to do so. If they are forced by the proposed PEL to be enacted to curtail or discontinue use of RCF, the resulting loss would be substantial. If the Board feels it is necessary to regulate RCF, Paul Darnell and his company urges the Board to follow the lead of federal authorities and adopt an RCF PEL of 0.5 f/cc.

Response: The comment with respect to findings and risk of disease from exposure to RCF is addressed in responses to the letters of Kurt Blase (Comment KB2) and of Dean Venturin (Comment DV1). With regard to the assertion that Paul Darnell's company could not control employees exposures to RCF to the proposed PEL of 0.2 f/cc, while not stated by the commenter, the context suggests that the commenter believes his company could control exposures to RCF in their operations to 0.5 f/cc by engineering control measures, the PEL value he recommends. However, as noted in the response to the comment in Dean Venturin's letter (Comment DV5), that commenter's letter, and its attachments, indicates that exposures in the "furnace related" segment of the industry can frequently exceed 0.5 f/cc, and engineering control measures are generally not available for these operations.

Therefore, it appears likely that to be confident of complying with a PEL of either 0.2 f/cc, or 0.5 f/cc, employees conducting work in the "furnace related" segment of the industry will need to wear respirators, with the result that for this industry segment there is probably not a significant difference in the costs or difficulty of compliance with these two possible PEL values.

Aileen (Chuca) Meyer, Pillsbury Winthrop Shaw Pittman LLP for Refractory Ceramic Fibers Coalition, by electronic mail dated March 19, 2009

Comment: During the public hearing, in connection with the discussion of feasibility of the proposed PEL for RCF, Board Member Frisch asked what percentage of exposure samples taken for RCF fell below the proposed PEL of 0.2 f/cc. This information is provided in a chart in this comment, dividing the information between results at manufacturing sites and customer sites. The information for samples taken in California is also provided, the percentages of air samples with results below the proposed PEL of 0.2 f/cc for samples in the time periods 1993-2008 and 1998-2008 are the same at 56%.

Response: The Board thanks Aileen Meyer for this additional information in reply to the inquiry of Board Member Frisch at the public hearing.

Vinyl bromide; bromoethylene

Julia Quint, by letter dated March 18, 2009

Comment: Julia Quint opposes the proposed PEL of 0.1 ppm 8-hour TWA for vinyl bromide because based on a comparison with vinyl chloride, the risk of developing cancer from exposure to vinyl bromide at 0.1 ppm will be greater than 4/1,000 workers exposed over their working lifetime. The commenter notes that the proposed PEL is not adequately protective because it was derived using a cancer unit risk value for vinyl bromide from Storm and Rozman that is relatively low, and that while EPA and OEHHA have not published cancer unit risk values for vinyl bromide, it is structurally similar to vinyl chloride which is a known carcinogen, and is metabolized to similar mutagenic compounds, and also causes liver cancer in animals. Julia Quint notes further that the Committee and the Storm and Rozman article cited in the comment consider vinyl bromide to be a more potent carcinogen than vinyl chloride. The commenter supports a PEL of 0.02 ppm based on the cancer Unit Risk Value for vinyl chloride.

Response: The Board does not believe there has been sufficient evaluation of the information presented by the commenter to support adoption of the PEL that she suggests for this substance. The Board notes that federal OSHA does not have a PEL for vinyl bromide. The proposed PEL of 0.1 ppm is a 50-fold reduction from the current California PEL of 5 ppm, and is one-fifth the current ACGIH TLV of 0.5 ppm. Julia Quint's suggested PEL would be a 250-fold reduction from the current PEL. The commenter suggests a PEL for vinyl bromide of 0.02 ppm based on a cancer risk assessment for a structurally related substance, vinyl chloride, reported by OEHHA in 2005. Julia Quint's conclusion from the OEHHA risk assessment is that the current PEL of 1 ppm for vinyl chloride, a California and federal OSHA standard with comprehensive carcinogen control requirements, poses a risk of 39 excess cancer cases per 1,000 workers. The OEHHA risk assessment document cited by the commenter was not released until after the deliberations of the Committee had concluded and such an advisory committee process should be used to revisit this new document in relation to all the significant documentation before considering further revision.

The Board believes that the Committee did reasonably consider the information available to it at the time and the current proposal is more protective than the current PEL, federal OSHA and the ACGIH TLV. Therefore, the Board declines to make any changes to the PEL proposal in response to this comment. However, the Division will take the comment under consideration for a future advisory committee and rulemaking if appropriate.

Michael Smith, WorkSafe, and 12 Co-Signers, by letter dated March 19, 2009

Comment: The commenters oppose the proposed PEL of 0.1 ppm 8-hour TWA for vinyl bromide and suggest that the best science available supports a PEL of 0.03 ppm or lower for this substance known to cause liver cancer. The commenters suggests that in the absence of a cancer Unit Risk Value for vinyl bromide, the value for vinyl chloride should be used, yielding a PEL of 0.03 ppm. The commenters suggest that since the minutes of the Committee's discussion of vinyl bromide reflect concern that vinyl bromide is most likely a more potent carcinogen than vinyl chloride, a value of 0.03 ppm based on the vinyl chloride cancer Unit Risk Value is appropriate for the PEL.

Response: See the response above to Julia Quint's written comment for this substance.

Vinyl fluoride

Julia Quint, by letter dated March 18, 2009

Comment: Julia Quint opposes the proposed PEL of 0.2 ppm 8-hour TWA for vinyl fluoride because, based on a comparison with vinyl chloride, the risk of developing cancer from exposure to vinyl fluoride at 0.2 ppm will be significantly greater than 1/1,000 workers used in the derivation of PELs for other regulated carcinogens such as hexavalent chromium and methylene chloride. The commenter notes that the proposed PEL is not adequately protective because it was derived using a cancer unit risk value from Storm and Rozman that is relatively low, and that while EPA and OEHHA have not published cancer unit risk values for vinyl fluoride, it is structurally similar to vinyl chloride and also causes liver cancer in animals.

Julia Quint supports a PEL of 0.06 ppm for vinyl fluoride based on a comparison of its risk with vinyl chloride and the assumption that it may be less potent than vinyl chloride and vinyl bromide as was noted in the Initial Statement of Reasons. The commenter believes that a PEL of 0.06 ppm for vinyl fluoride is consistent with a risk level of 1/1,000 workers. The commenter also notes that derivation of a PEL based on noncancer effects in the rat liver yields a value of 0.08 ppm 8-hour TWA, which is supportive of a PEL based on prevention of cancer at a level of 0.06 ppm as the commenter recommends.

Response: The Board does not believe there has been sufficient evaluation of the information presented by the commenter to support adoption of the PEL she suggests for this substance. The Board notes that federal OSHA does not have a PEL for vinyl fluoride. The proposed PEL of 0.2 ppm is one-fifth the current ACGIH TLV of 1 ppm. Julia Quint suggests a PEL for vinyl fluoride of 0.06 ppm based on a cancer risk assessment for a structurally related substance, vinyl chloride, reported by OEHHA in 2005. Julia Quint's conclusion from the OEHHA risk assessment is that the current PEL of 1 ppm for vinyl chloride, a California and federal OSHA standard with comprehensive carcinogen control requirements, poses a risk of 39 excess cancer cases per 1,000 workers.

The OEHHA risk assessment document cited by the commenter was not released until after the deliberations of the Committee had concluded and such an advisory committee process should be used to revisit this new document in relation to all the significant documentation before considering further revision.

The Board believes that the Committee did reasonably consider the information available to it at the time and the current proposal is more protective than the current PEL, federal OSHA and the ACGIH TLV. Therefore, the Board declines to make any changes to the PEL proposal in response to this comment. However, the Division will take the comment under consideration for a future advisory committee and rulemaking if appropriate.

Michael Smith, WorkSafe, and 12 Co-Signers, by letter dated March 19, 2009

Comment: The commenters oppose the proposed PEL of 0.2 ppm 8-hour TWA for vinyl fluoride and urge that the PEL for this substance be set no higher than 0.03 ppm based on the cancer Unit Risk Value for vinyl chloride as they also suggested for vinyl bromide. The commenters note that although there is reason to believe vinyl fluoride is a less potent carcinogen than vinyl bromide and possibly vinyl chloride, it is improper to arbitrarily multiply the PEL for vinyl chloride in the absence of knowledge of whether that will adequately protect workers. The commenters suggest that the precautionary principle militates for a PEL to be set at a level similar to a strong PEL for vinyl chloride in order to significantly reduce risk of cancer from exposure. And conversely, that setting a PEL, even a little too high, could increase cancer incidence among

dozens of workers over a lifetime, with the effect being magnified by the fact that vinyl fluoride is a "High Production Volume Chemical" with over one million pounds produced annually in the United States.

Response: See the response above to the written comment of Julia Quint.

ADDITIONAL DOCUMENTS RELIED UPON

None.

ADDITIONAL DOCUMENTS INCORPORATED BY REFERENCE

None.

DETERMINATION OF MANDATE

This standard does not impose a mandate on local agencies or school districts as indicated in the Initial Statement of Reasons.

ALTERNATIVES CONSIDERED

The Board invited interested persons to present statements or arguments with respect to alternatives to the proposed standards. No alternative considered by the Board would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the adopted action.